

EXHIBIT B

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4

IN RE: ETHICON, INC.,)
5 PELVIC REPAIR SYSTEM) Master File No.
PRODUCTS LIABILITY) 2:12-MD-02327
6 LITIGATION) MDL No. 2327

* * * * *

7 MELISSA RIDGLEY and)
ERIC RIDGLEY,) Case No.
8) 2:12-cv-01311
 Plaintiffs,)
9 Vs.)
) JOSEPH R. GOODWIN
10 ETHICON, INC., ETHICON) US DISTRICT JUDGE
WOMEN'S HEALTH AND)
11 UROLOGY, a Division of)
Ethicon, Inc., GYNECARE,)
12 and JOHNSON & JOHNSON,)
Defendants.)

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14
15

DEPOSITION OF: Scott Serels, M.D.
16 DATE: April 7, 2016
HELD AT: Courtyard Norwalk
17 474 Main Avenue
Norwalk, Connecticut

18
19

20 Reporter: Robin Balletto, RMR, LSR #230

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23 GOLKOW TECHNOLOGIES, INC.
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Scott Serels, M.D.

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1 (Deposition commenced at 4:35 p.m.)

2

3 Scott Serels, M.D., Witness, having been first
4 duly sworn by Robin Balletto, RMR, a Notary
5 Public in and for the State of Connecticut,
6 was examined and testified as follows:

7

8 DIRECT EXAMINATION BY MR. FAES

9

10 Q Good afternoon, Doctor. My name is Andy
11 Faes, and I represent the Plaintiffs in this
12 litigation, and I'm here now to take your deposition
13 regarding your TVT general report. Do you understand
14 that?

15 A I do.

16 Q You understand that you're under oath and
17 sworn to tell the truth, correct?

18 A I do.

19 Q And if I ask you a question that for any
20 reason you don't understand, or it doesn't make sense
21 to you, please just let me know and I'll try to
22 rephrase the question, okay?

23 A Okay.

24 Q Have you ever been deposed before?

1 A I have.

2 Q How many times?

3 A I would say maybe four times in the last
4 year.

5 Q And were those for mesh cases?

6 A There was some mesh cases involved.

7 Q What mesh cases were you deposed on?

8 A They were all medical malpractice cases.
9 They weren't specifically for a specific type of mesh.

10 Q And what was your role in those cases?

11 A I played -- I helped the defendants and I
12 helped the plaintiffs.

13 Q So you testified as an expert for the
14 plaintiffs in one case and an expert for the defendants
15 in one case?

16 A Correct, different cases.

17 Q And what were the other two depositions that
18 you testified in the last year that were not medical
19 malpractice?

20 A They dealt with copyright of pharmaceuticals.

21 Q And what was your role in that case?

22 A Expert.

23 Q So I'll assume you understand the rules of
24 the deposition, that any time I ask you a question, you

1 try to answer it yes or no, not uh-huh or uh-uh, please
2 answer verbally.

3 A Yes.

4 Q So that the court reporter can make a clean
5 record.

6 (Plaintiff's Exhibit 1, Notice of
7 Deposition: Marked for Identification.)

8 BY MR. FAES:

9 Q Doctor, I'm going to hand you what's been
10 marked as Exhibit number 1 to your deposition and ask
11 you, have you seen that document before?

12 A I have.

13 Q And you've reviewed the list of document
14 requests that are attached to your notice of
15 deposition?

16 A I did.

17 Q Have you brought any documents with you today
18 that are responsive to that notice?

19 A I did. I had my expert report and my
20 curriculum vitae.

21 Q And those are the same that were served
22 originally, correct? There haven't been any changes or
23 updates to that since they were served, correct?

24 A There may have been an update to the CV. I'm

1 not sure you have the most recent copy of it.

2 Q We may mark that in a minute. Have you sent
3 a bill for any of your work in this case to Ethicon and
4 Johnson & Johnson or their attorneys?

5 A I did.

6 Q And how many hours have you billed so far in
7 this case?

8 MR. DIPOLA: Object to form.

9 THE WITNESS: Three or four hours.

10 BY MR. FAES:

11 Q So you've only billed three to four hours for
12 preparing your general TVT report in this case?

13 A Yes.

14 Q And that includes all the time you spent
15 reviewing materials as well as drafting the report?

16 A Correct.

17 Q And how many hours have you spent on the one
18 case specific, the report that you prepared in this
19 litigation?

20 A Probably two hours or so. Two or three
21 hours.

22 Q And what was your hourly rate for preparing
23 those expert reports?

24 A \$450 an hour.

1 Q Is there an agreement that you have with
2 Ethicon or Johnson & Johnson and their counsel that
3 sets forth your hourly billing rates for various types
4 of activities?

5 A Yes.

6 Q Have you brought that with you here today?

7 A I have not.

8 MR. FAES: We request that we get a copy
9 of that agreement.

10 BY MR. FAES:

11 Q Doctor, is your billable rate different for
12 deposition testimony?

13 A For a full deposition it would be, yes.

14 Q And what is that rate?

15 A Usually it's \$5,000 a day.

16 Q And will you be charging \$5,000 a day for
17 your deposition testimony given today?

18 A Probably not.

19 Q What do you anticipate you'll bill for your
20 deposition testimony today?

21 A Probably be an hourly rate.

22 MR. DIPOLA: Object to form.

23 BY MR. FAES:

24 Q Do you have a set rate for your testimony at

1 trial if you were to give testimony at trial?

2 A It would probably be similar to the
3 deposition rate per day.

4 Q Doctor, you mentioned earlier that you've
5 testified in two medical malpractice cases in the last
6 year, once for the plaintiff and once for the
7 defendant?

8 A Correct.

9 Q How long have you been doing expert
10 litigation consulting work?

11 A I would say the past eight years.

12 Q How many times would you say you've testified
13 in court?

14 A Four.

15 Q Four times. Do you remember offhand what
16 those instances were?

17 A What they were. Not completely, but the more
18 recent ones I remember more completely.

19 Q Do you recall if any of those four instances
20 involved the use of surgical mesh?

21 A Yes.

22 Q Do you remember how many of those four times
23 were involving the use of surgical mesh? Was it once
24 or twice or three times if you recall?

1 A If I had to say for certain -- well,
2 certainly I couldn't say, but I would say at least one
3 had a patient that involved mesh.

4 Q Do you recall the name of the person involved
5 in that or any of the attorneys involved?

6 A No.

7 Q Doctor, do you keep time sheets or
8 itemizations of the work you've done on your TVT report
9 in this case?

10 A Yes.

11 Q And have you brought those with you here
12 today?

13 A I have not.

14 MR. FAES: Again, we would ask that
15 those be produced.

16 What I'm going to go ahead and do is I'm
17 going to mark as Exhibit 2 a placeholder document for
18 all of the invoices that you've submitted to Ethicon
19 and Johnson & Johnson and/or their attorneys in this
20 case.

21 Can I get an agreement from counsel that
22 we'll get those invoices to the court reporter to make
23 them a part of the official record of this deposition,
24 all the invoices that have been billed thus far as of

1 today's date.

2 MR. DIPOLA: Invoices, no problem.

3 (Plaintiff's Exhibit 2, Placeholder for
4 Invoices: Marked for Identification.)

5 BY MR. FAES:

6 Q So Doctor, you stated that you estimate that
7 you spent three to four hours preparing your TVT
8 general report in this case?

9 A Yes.

10 Q How many of those three to four hours do you
11 estimate was spent in actually drafting your report?

12 MR. DIPOLA: Object to form.

13 THE WITNESS: I would say the majority
14 was probably spent drafting the report, 80 percent of
15 the three to four hours.

16 BY MR. FAES:

17 Q So the remaining time you believe
18 approximately one to two hours was spent in reviewing
19 materials that went into your report?

20 A Yes, maybe perhaps looking over some articles
21 that I was less familiar with.

22 Q And how much time did you spent with defense
23 counsel preparing for your deposition today?

24 A Approximately two hours.

1 Q Do you intend to bill that at your \$450 an
2 hour rate?

3 A Yes.

4 Q Did you have any other meetings with defense
5 counsel preparing for your deposition other than today?

6 A No.

7 Q No meetings over the phone or anything like
8 that leading up to this deposition?

9 A No.

10 Q Doctor, I'm going to mark a couple of things
11 here, because I'm limited in time, and I don't know
12 if the -- I'm not sure if the version of the CV you
13 brought today is different from the one that was served
14 or not. So I'm going to mark as Exhibit 3 the CV that
15 you brought with you today and the CV that was produced
16 earlier with your expert report as Exhibit 4.

17 (Plaintiff's Exhibit 3, CV: Marked for
18 Identification.)

19 (Plaintiff's Exhibit 4, CV attached to
20 Expert Report: Marked for Identification.)

21 BY MR. FAES:

22 Q And I'll actually have you look at Exhibit 3.
23 Doctor, what is Exhibit 3?

24 A Exhibit 3 is my CV.

1 Q And is that your current and updated CV?

2 A That is.

3 Q When was this CV last updated?

4 A I would say October of 2015.

5 Q Now, Doctor, on the third page of your CV
6 there's a section entitled pelvic prolapse and
7 incontinence courses.

8 A Yes.

9 Q Do you see that?

10 A I do.

11 Q Do you recall when you added this particular
12 section to your CV?

13 A I would say four or five years ago.

14 Q So you believe it was added some time in
15 2011?

16 A Yes, somewhere around there.

17 Q And I notice that you list a number of
18 different products that you've given lectures on either
19 throughout the country or internationally. I don't see
20 the TVT product listed as one of the products that
21 you've given a lecture before.

22 MR. DIPOLA: Objection. Misrepresents.

23 BY MR. FAES:

24 Q First of all, is TVT on this list of products

1 that you've given lectures on throughout the country or
2 internationally?

3 A It's not on this list, no.

4 Q Is there any particular reason why?

5 A Yes.

6 Q Why is that?

7 A These are more of the current or cutting edge
8 therapies that were being offered at the time. TVT
9 retropubic was really the gold standard that had
10 been -- that predated a lot of the more recent courses.
11 So it wasn't something that was commonly taught as a
12 primary course within the last say ten years.

13 Q So I take it, have you given lectures on the
14 TVT?

15 A Absolutely. Yes, absolutely.

16 Q Let me finish my question, sorry.

17 A My apologies.

18 Q Is it true that you've given lectures on the
19 TVT for Ethicon both throughout the country and
20 internationally?

21 A Throughout the country and internationally,
22 yes, that's correct.

23 Q Is it true that you've given lectures on the
24 TVT-O for Ethicon throughout the country and

1 internationally?

2 A That is correct as well.

3 Q I also don't see the Solyx sling listed on
4 here. The Solyx, you've published three articles
5 regarding the Solyx sling; is that correct?

6 A Correct.

7 Q Is there any particular reason why that's not
8 listed on the section of your CV that lists lectures
9 that you've given throughout the U.S. and Europe?

10 A Maybe we have different copies, but the
11 second line down on page three says, Lecture for Solyx
12 throughout U.S. and Europe. So maybe you don't have
13 that.

14 Q Let me take a look at that if you don't mind.

15 A That I didn't think changed, but who knows.

16 MR. FAES: It's in bold that's why I
17 missed it.

18 (Plaintiff's Exhibit 5, CV from
19 Ethicon's production Bates 19361638 though 645: Marked
20 for Identification.)

21 BY MR. FAES:

22 Q Doctor, I'm going to hand you what's been
23 marked as Exhibit 5 to your deposition, and I'll
24 represent that this is a CV of yours that we found in

1 Ethicon's production. If you want to go ahead and take
2 a look at that. My best guess based on your list of
3 publications is that this was prepared some time around
4 2005. If you look at the top of the publication list,
5 the most recent publication is listed as 2005 and in
6 press. Do you see that?

7 A I do see that, yes, correct.

8 Q Do you have any reason to disagree with the
9 fact that this is probably your CV as of some time in
10 2005?

11 A Correct. I would agree that that probably is
12 true.

13 Q Now, on this particular CV you don't have a
14 list of the pelvic prolapse and incontinence courses
15 that is listed on your current CV. Do you see that?

16 A I do.

17 Q Is there any particular reason why you didn't
18 include those on your CV in 2005?

19 A I just didn't think it relevant at the time.

20 Q Is there any particular reason why you chose
21 to add those items in 2011?

22 A At the time I thought it was an interesting
23 find that I had taught on so many different alternative
24 procedures, and I thought that might be interesting for

1 someone who is looking at my CV.

2 Q Now, you also are a lecturer for
3 pharmaceutical products as well, right, not just pelvic
4 prolapse and incontinence products?

5 A Correct.

6 Q Is there any particular reason why you chose
7 to list your products that you've lectured for on
8 pelvic organ prolapse and SUI, and not on
9 pharmaceutical products that you've lectured on?

10 A No particular reason.

11 Q For example, and I'm going to butcher the
12 pronunciation on this, you've given lectures on the
13 drug Myrbetriq. Maybe you can pronounce it, and the
14 court reporter might appreciate you spelling it for me.

15 A I think you're referring to Myrbetriq,
16 M-Y-R-B-E-T-R-I-Q.

17 Q And you have given lectures on that product
18 as well, right?

19 A I have.

20 Q In fact, you've done at least seven speaking
21 events on Myrbetriq for Astellas Pharmaceuticals in
22 2014 alone, correct?

23 A That's probably correct. I don't have the
24 exact numbers.

1 Q Is it correct that you were paid at least
2 \$2,700 by Astellas for each one of those lectures?

3 A I don't recall the exact amount. It sounds
4 high, but I don't know for sure.

5 Q Sitting here today do you have any reason to
6 dispute that amount of \$2,700?

7 A I just don't know.

8 MR. DIPOLA: Object to form.

9 BY MR. FAES:

10 Q Now, you've done both -- strike that.
11 You've done expert work for both plaintiffs
12 and defendants, correct?

13 A Correct.

14 Q Do you have an kind of an estimation of what
15 percentage of the time you've served as an expert for
16 plaintiffs as opposed to the defendants?

17 A I don't know exactly, but it probably is a
18 little bit more heavy toward the defendants.

19 Q Can you estimate a percentage of the time
20 that you do work for the defendants as opposed to the
21 plaintiffs?

22 A If I had to guess, I couldn't tell you
23 exactly, but probably 70 percent was defendant cases
24 versus 30 percent for the plaintiffs.

1 Q Now, you're a urologist, so do you treat men
2 as well as women?

3 A I do.

4 Q What percentage of your practice would you
5 say is treating men as opposed to women?

6 A I would say 15 to 20 percent men versus 80 to
7 75 percent women. Eighty to 85 percent women.

8 Q Now, I just wanted to ask you about one other
9 thing on your CV. On the front page I note that you
10 did a rotation in female urology with Dr. Shlomo Raz in
11 1997?

12 A I did, that's correct.

13 Q Do you know Dr. Raz pretty well?

14 A Pretty well.

15 Q Would you agree that Dr. Raz is one of the
16 most respected pelvic floor surgeons in the country?

17 A I agree.

18 Q Would you agree that Dr. Raz is an expert in
19 treating complications from pelvic mesh?

20 MR. DIPOLA: Object to form.

21 THE WITNESS: I agree.

22 BY MR. FAES:

23 Q Doctor, would you agree that you've been an
24 advocate for certain pelvic mesh products manufactured

1 by American Medical Systems?

2 MR. DIPOLA: Object to form.

3 THE WITNESS: I advocate the products
4 that I think are good products and useful for the way I
5 treat patients.

6 BY MR. FAES:

7 Q Does that include products that are
8 manufactured by AMS?

9 MR. DIPOLA: Object to form.

10 THE WITNESS: It did.

11 BY MR. FAES:

12 Q But it doesn't any longer?

13 A It does. AMS has certainly morphed into
14 other companies.

15 Q Would you agree that you've been an advocate
16 for products manufactured by Boston Scientific?

17 A I would.

18 (Plaintiff's Exhibit 6, Expert Report:
19 Marked for Identification.)

20 BY MR. FAES:

21 Q Doctor, I'm going to mark Exhibit Number 6 to
22 your deposition. Doctor, can you tell me what that is?

23 A That's my expert report.

24 Q Doctor, does this report contain all of the

1 opinions you intend to offer in this case regarding the
2 TVT product?

3 A Yes.

4 Q Now, Doctor, in this report you discuss
5 various facts and cite various facts. Did you discuss
6 the facts in your report that you felt were most
7 important to rendering your opinions in this case?

8 A Yes.

9 Q You also cite a number of articles and
10 materials in your report. Is there any particular
11 reason why you chose to cite the materials you did
12 within your expert report?

13 A I thought they were most applicable to my
14 expertise.

15 (Plaintiff's Exhibit 7, Reliance List:
16 Marked for Identification.)

17 BY MR. FAES:

18 Q Doctor, I'm going to mark Exhibit number 7 to
19 your deposition. Can you tell me what that is?

20 A It's a reliance list of additional materials
21 referenced in the report.

22 Q Between this and the articles that --
23 articles and items that are cited specifically in your
24 general report, is this a list of all the materials

1 that you intend to rely upon in -- strike that.

2 Doctor, between this reliance list marked as
3 Exhibit number 7 and the materials specifically cited
4 in your expert report, do those contain all of the
5 materials that you've reviewed and relied upon in
6 forming your opinions in this case?

7 A Yes.

8 MR. DIPOLA: Doctor, did you bring the
9 thumb drive?

10 THE WITNESS: I did.

11 MR. DIPOLA: There is an amended
12 reliance list that I told you about prior to the
13 deposition starting that has the reliance list on it,
14 the amended reliance list.

15 MR. FAES: So there's a reliance list on
16 the thumb drive that I haven't seen yet?

17 MR. DIPOLA: There is, but it's a
18 portion of that. This is over-inclusive, the thumb
19 drive is under-inclusive.

20 MR. FAES: Where is the thumb drive?
21 Can we get it out.

22 MR. DIPOLA: Sure. That's the one that
23 has the password that I explained to you before.

24

1 (Plaintiff's Exhibit 8, Thumb Drive:
2 Marked for Identification.)

3 BY MR. FAES:

4 Q Doctor, I'm going to mark the flash drive
5 that you've just handed to me as Exhibit number 8 to
6 your deposition. Can you explain to me what that is?

7 A Again, as stated by my counsel, or the
8 counsel, that it's just a list of the references that's
9 in slight abbreviated form to the list that you handed
10 me for Exhibit 7.

11 Q Is there anything contained on the flash
12 drive marked as Exhibit number 8 that is not already
13 listed in your reliance list marked as Exhibit number
14 7?

15 A Not that I'm aware of.

16 Q Doctor, who prepared your reliance list which
17 has been marked as Exhibit number 7?

18 A The reliance list was prepared in combination
19 with the law firm representing the defendant.

20 Q So who would you say prepared it? Would you
21 say that you prepared it --

22 A It was in combination. Sorry to interrupt
23 you. Yes, it's a combination of some of the references
24 I was looking for, I asked them to look up some things,

1 and we compiled the two.

2 Q Doctor, I just want to ask you a few
3 questions about the products that you're currently
4 using in clinical practice. Can you tell me what
5 products -- let me rephrase it.

6 Can you tell me what polypropylene sling
7 products you currently use for the treatment of stress
8 urinary incontinence?

9 A Meaning the manufacturers of the products, or
10 just the types of products.

11 Q The manufacturers and the type. For example,
12 I know that Monarc is made by AMS, so I don't
13 necessarily need you to tell me the Monarc by AMS. I'm
14 just more looking for the name of the product if you
15 know.

16 A Okay. So I use a variety of midurethral
17 slings, some of which are put into a single incision,
18 some of which are put into an obturator placement, and
19 some of which are put in retropubically. The various
20 names of the slings, in short, the manufacturer of the
21 slings are Boston Scientific, American Medical System,
22 Caldera, and Gynecare.

23 Q Which midurethral polypropylene sling would
24 you say you use the most often?

1 MR. DIPOLA: Object to form.

2 THE WITNESS: Quite honestly, I could
3 put in any of these slings accurately, so I use a
4 variety depending on what the hospital has, or what the
5 surgery center has, and that does seem to change more
6 often. So currently probably more Caldera and Boston
7 Scientific.

8 BY MR. FAES:

9 Q Doctor, what synthetic mesh products do you
10 currently use for the treatment of pelvic organ
11 prolapse?

12 MR. DIPOLA: Objection. Beyond the
13 scope.

14 THE WITNESS: For the most part I do not
15 use products unless I'm doing an abdominal approach.

16 BY MR. FAES:

17 Q And what products do you use for the
18 abdominal approach?

19 MR. DIPOLA: Same objection.

20 THE WITNESS: It would be a
21 polypropylene mesh. Where it comes from, who
22 manufacturers it, it could vary depending, again, on
23 what the hospital has, could be Caldera, could be Bard,
24 could be Gynecare, could be Boston Scientific.

1 BY MR. FAES:

2 Q So is it fair that you don't have a
3 particular product that you reach for if you're doing
4 abdominal repair for pelvic organ prolapse? There's
5 not one that you --

6 A Correct. They're fairly interchangeable.

7 Q And is the same true of polypropylene slings,
8 there isn't one that you have a particular preference
9 for?

10 A Not out of the ones that I've mentioned.

11 Q Doctor, have you ever performed a Burch
12 procedure?

13 A I have.

14 Q And when was the last -- strike that. Was
15 the first time you performed a Burch procedure?

16 A The first Burch probably '97.

17 Q And when was the last time you believe you
18 performed a Burch procedure?

19 A 2015.

20 Q So you performed a Burch procedure within the
21 last six months?

22 A In the last year.

23 Q When is the last time you've performed a
24 biologic tissue sling procedure?

1 A Again, probably within the last year.

2 Q Doctor, would you agree that you don't hold
3 yourself out as an academic physician?

4 MR. DIPOLA: Object to form.

5 THE WITNESS: I have several academic
6 appointments, so I'm not sure how you qualify an
7 academic physician, but I am a clinician who has
8 academic appointments.

9 BY MR. FAES:

10 Q Would you agree that you don't hold yourself
11 out as an expert in chemical engineering?

12 A That I would agree on.

13 Q Would you agree that you don't hold yourself
14 out as an expert in surgical pathology?

15 A I agree with you on that.

16 Q Would you agree that you don't hold yourself
17 out as an expert in polymer chemistry?

18 A Yes. I agree I'm not an expert in polymer
19 chemistry.

20 Q Would you agree that you have no background
21 in polymer chemistry?

22 A Yes, I would agree with that.

23 Q Have you ever done bench testing research on
24 any polypropylene surgical mesh?

1 A No.

2 Q Have you ever done any lab research on
3 polypropylene surgical mesh?

4 A No.

5 Q Have you ever done any type of pathological
6 analysis on explanted polypropylene mesh?

7 A No.

8 Q Would you agree that you don't hold yourself
9 out as a biomaterials specialist?

10 A I would agree.

11 Q Would you agree that you've never published
12 opinions that polypropylene does not degrade in the
13 human body?

14 A I would agree.

15 Q Would you agree that you've never studied
16 polypropylene under a microscope to see if it degrades?

17 MR. DIPOLA: Object to form.

18 THE WITNESS: I would agree.

19 BY MR. FAES:

20 Q Would you agree that you've never done a
21 chemical analysis of polypropylene to see whether or
22 not it degrades?

23 MR. DIPOLA: Same objection.

24 THE WITNESS: I have not studied that,

1 correct.

2 BY MR. FAES:

3 Q Would you agree that you don't hold yourself
4 out as an expert on warnings as it relates to medical
5 devices?

6 MR. DIPOLA: Object to form.

7 THE WITNESS: I would agree on that
8 general statement.

9 BY MR. FAES:

10 Q Do you know what standards govern the risk
11 information that medical device companies are required
12 to put in their IFUs or instructions for use?

13 A I am not sure.

14 Q Do you know what industry standards govern
15 warnings on medical devices?

16 A Again, I'm not sure of the exact guidelines.

17 Q Do you know what departments of a medical
18 device company are involved in creating warnings for
19 medical devices?

20 MR. DIPOLA: Object to form.

21 THE WITNESS: Again, I'm not sure.

22 BY MR. FAES:

23 Q Do you know what the FDA's requirements are
24 regarding warnings for medical devices?

1 A I do not know.

2 MR. DIPOLA: Same objection.

3 BY MR. FAES:

4 Q Have you ever drafted or been involved in
5 drafting an IFU or instructions for use for a medical
6 device?

7 A I've helped with the steps for -- procedural
8 steps in an IFU for a device.

9 Q Have you ever drafted or been involved in
10 drafting the warnings and precautions section or the
11 adverse reactions section of the IFU for a medical
12 device?

13 A No.

14 Q Have you ever been involved in drafting an
15 IFU for a prescription drug?

16 MR. DIPOLA: Object to form.

17 THE WITNESS: No.

18 BY MR. FAES:

19 Q Would you agree or disagree that physicians
20 should be made aware of all the significant safety
21 risks associated with a medical device in the IFU or
22 instructions for use?

23 MR. DIPOLA: Object to form. Vague.

24 THE WITNESS: I agree that people should

1 be made aware of any possible complications.

2 BY MR. FAES:

3 Q Would you agree or disagree that the
4 manufacturer of a medical device that will be implanted
5 in a woman's body is required to disclose all
6 significant risks to doctors that come with the use of
7 that device?

8 MR. DIPOLA: Objection. Assumes facts
9 not in evidence.

10 THE WITNESS: The way you stated it, I
11 would agree.

12 BY MR. FAES:

13 Q Doctor, would you agree that you don't hold
14 yourself out as a biomedical engineer?

15 A I agree with that.

16 Q Do you know what standards or operating
17 procedures manufacturers must follow in designing mesh
18 products?

19 MR. DIPOLA: Objection. Asked and
20 answered.

21 THE WITNESS: No.

22 BY MR. FAES:

23 Q Do you know what responsibilities the
24 manufacturer holds in designing mesh products?

1 MR. DIPOLA: Same objection.

2 THE WITNESS: No.

3 BY MR. FAES:

4 Q Doctor, do you know what a design and failure
5 modes effects analysis is?

6 A No.

7 Q So I would assume since you don't know what a
8 design failure modes effects analysis is, I wouldn't
9 expect you to offer any opinions in this case regarding
10 how that analysis should be done, or what should or
11 should not be included in that analysis, correct?

12 MR. DIPOLA: Object to form.

13 THE WITNESS: When you say explained, I
14 could always raise an opinion.

15 BY MR. FAES:

16 Q But sitting here today --

17 A Yes.

18 Q -- you don't know what a design failure modes
19 effects analysis is, correct?

20 A Correct.

21 Q Doctor, do you know what a process failure
22 modes effects analysis is?

23 A No.

24 Q And again, since you don't know what a

1 process failure modes effects analysis is, can I assume
2 that at this time you don't intend to offer any
3 opinions on this regarding how that analysis should be
4 done or what should be included in that analysis,
5 correct?

6 A Correct.

7 Q Doctor, do you know what an application
8 failure modes effect analysis is?

9 A No.

10 Q And again, since you don't know what an
11 applications failure modes effects analysis is, at this
12 time you don't intend to offer any opinions regarding
13 what that analysis should involve or what should or
14 should not be in that analysis, correct?

15 A Correct.

16 Q Doctor, do you know if you've reviewed the
17 design history file for the TVT product?

18 MR. DIPAOLO: Object to form.

19 THE WITNESS: No. I have not seen it.

20 BY MR. FAES:

21 Q Doctor, do you know what ISO testing is, or
22 ISO standards?

23 A No.

24 Q Doctor, have you ever reviewed any of

1 Ethicon's internal standard operating procedures
2 related to the design of medical devices?

3 MR. DIPOLA: Object to form. Asked and
4 answered.

5 THE WITNESS: No.

6 BY MR. FAES:

7 Q Do you have an understanding of how long it
8 takes a medical device to get to market?

9 A I have some understanding.

10 Q And what's your understanding of how long
11 that typically takes?

12 A Well, I would say at least five to ten years.

13 Q Would you agree that if a device took less
14 than five years to get to market, that would be fairly
15 rapid compared with your understanding of how long it
16 typically takes?

17 MR. DIPOLA: Objection to form.
18 Misstates facts.

19 THE WITNESS: No.

20 BY MR. FAES:

21 Q Doctor, do you own any patents for the design
22 of medical devices?

23 A No.

24 Q Doctor, do you know what a clinical expert

1 report is?

2 A I do.

3 Q Can you explain to me what you believe a
4 clinical expert report is, at least as it relates to
5 the TVT?

6 A I think it would represent a report given by
7 an expert who would establish their credentials in the
8 field in terms of their use of various products in
9 their practice as well as throughout their peer
10 network, and in so doing that report it would
11 incorporate some of the other findings that other
12 physicians have used to study those devices in their
13 clinical practice.

14 Q Do you recall sitting here today if you've
15 reviewed the clinical expert report for the TVT
16 product?

17 MR. DIPOLA: Object to form.

18 THE WITNESS: Whose expert report?

19 BY MR. FAES:

20 Q Any of the clinical expert reports produced
21 by Ethicon?

22 A I would say yes.

23 Q Do you recall which versions you reviewed?

24 MR. DIPOLA: Object to form.

1 THE WITNESS: No.

2 BY MR. FAES:

3 Q Do you recall if you've reviewed the clinical
4 expert report for the laser cut mesh product?

5 MR. DIPOLA: Object to form.

6 THE WITNESS: I do not recall seeing
7 that.

8 BY MR. FAES:

9 Q Doctor, have you ever explanted a mesh
10 product before?

11 A I have.

12 Q How many times during the course of your
13 career would you say you've explanted a mesh product?

14 A Many.

15 Q Do you have any kind of a number?

16 A I would say in a given year could be 20.

17 Q So you believe you average about 20 a year?

18 A Probably.

19 Q When do you believe you first started
20 explanting mesh products?

21 MR. DIPOLA: Object to form.

22 THE WITNESS: Since they've been used.

23 BY MR. FAES:

24 Q Would it be fair to estimate that you've

1 explanted at least 200 mesh products during the course
2 of your career?

3 MR. DIPAOLA: Object to form.

4 THE WITNESS: Yes, I would say that's
5 probably accurate, but you have to realize that my
6 practice is different than the average. People are
7 sent to me specifically to have their complications
8 remedied, such as erosion or a problem with mesh.

9 BY MR. FAES:

10 Q How many days of the week would you say you
11 operate, Doctor?

12 A Two.

13 Q And what percentage of your practice is
14 related to the treatment of stress urinary incontinence
15 in women, do you believe?

16 A Say 25 percent.

17 Q And what percent of your practice is related
18 to treating complications from pelvic mesh?

19 MR. DIPAOLA: Objection to form.

20 THE WITNESS: Five percent.

21 BY MR. FAES:

22 Q Have you ever explanted a TVT product?

23 A I have.

24 Q How many times do you believe you've

1 explanted a TVT product?

2 A It's hard to give an absolute number, but --
3 it's hard to give you a number. A lot of times I may
4 see someone who has some kind of mesh complication, but
5 I really don't even know what product it was, so there
6 are times where I may not even know what I'm taking
7 out.

8 MR. FAES: Do you need to check that,
9 Doctor? We can go off the record if you do.

10 THE WITNESS: I'm fine.

11 BY MR. FAES:

12 Q Have you ever explanted a TVT-O product?

13 A I have.

14 Q Have you explanted a TVT Secure product?

15 A I have.

16 Q Have you explanted a TVT Abbrevio product?

17 A Not that I know of.

18 Q Have you explanted a TVT Exact product?

19 A Yes.

20 Q Have you implanted -- I know for -- sorry,
21 this is tedious, I'll have to go through the list.

22 You've obviously implanted personally the
23 TVT, the TVT-O, and the TVT Secure products before,
24 correct?

1 A Correct.

2 Q Have you implanted the TVT Abbrevio products
3 before?

4 A I have.

5 Q How many of those would you say you've
6 implanted during the course of your career?

7 A It wasn't one of my main products that I
8 would use, but have I done 20 of them, probably.

9 Q Have you implanted the TVT Exact product
10 during the course of your career?

11 A Again, it probably was somewhere around 20 or
12 30.

13 Q How many TVT products, and by that I mean the
14 TVT retropubic product that was --

15 A In total?

16 Q Do you believe that you've implanted in the
17 course of your career?

18 MR. DIPOLA: You mean separate from the
19 modifications? Vague? I'm sorry, object to form.
20 Vague.

21 BY MR. FAES:

22 Q So let me just rephrase it. Let me try to
23 get the whole question out.

24 How many TVT products, and by TVT products I

1 mean the TVT retropubic product that first came out in
2 1998 do you believe you've implanted during the course
3 of your career?

4 A Yes. I mean, I've implanted hundreds of TVT
5 products in the TVT family.

6 Q But specifically with regard to the TVT
7 retropubic classic product, do you know how many of
8 those you've implanted?

9 A Probably hundreds of the TVT retropubics
10 throughout the year.

11 Q What about the TVT-O?

12 A Again, hundreds.

13 Q And the TVT Secure?

14 A Hundreds.

15 Q Doctor, do you have surgical days that you
16 set aside each week for removals or treatment of mesh
17 complications?

18 A No.

19 Q When you have removed -- actually, first of
20 all, let me ask you this. Have you ever removed an
21 entire midurethral sling?

22 MR. DIPOLA: Object to form.

23 THE WITNESS: Yes.

24

1 BY MR. FAES:

2 Q How many times do you think you've done that?

3 A Dozens.

4 Q And what were the indications for the
5 removals of those slings?

6 A A variety of indications. Could be an
7 erosion, could be discomfort, could be retention.
8 Those are probably the top three.

9 Q Was pain ever an indication for some of those
10 removals?

11 A Yes.

12 Q Dyspareunia or painful sexual intercourse?

13 A Yes.

14 Q I take it in addition to the dozens or so of
15 slings that you've completely removed, there's been at
16 least 100 of meshes that you've treated by trimming or
17 revising the surgery; is that correct?

18 MR. DIPOLA: Object to form.

19 THE WITNESS: I wouldn't say hundreds,
20 but there have been others. But a lot of times if
21 we're going in, we'll take out most of the mesh, if not
22 all.

23 BY MR. FAES:

24 Q And what are the indications for when you

1 have to do a surgical revision of a prior mesh repair,
2 are they the same as when you do removals?

3 A Yes. Similar.

4 Q Have you ever had one of your patients with a
5 TVT device report chronic pain to you?

6 A Yes.

7 Q And you would agree that -- strike that.

8 Have you ever had one of your patients with a
9 TVT report painful sexual intercourse or dyspareunia to
10 you?

11 A Yes.

12 Q Have you ever seen one of your patients with
13 mesh that is roped or curled?

14 MR. DIPOLA: Object to form.

15 THE WITNESS: I've seen a patient with a
16 roped sling, yes.

17 BY MR. FAES:

18 Q Was it a TVT sling?

19 A I can't be sure.

20 Q Was it just one patient, or have you seen it
21 on more than one indication?

22 A I've seen it on more than one patient.

23 Q Do you recall how you typically treat a
24 patient with a roped or curled string?

1 A I would remove the majority of that sling
2 that was curled.

3 Q Have you ever seen one of your patients with
4 a polypropylene sling that is frayed?

5 MR. DIPOLA: Object to form.

6 THE WITNESS: Frayed?

7 BY MR. FAES:

8 Q Yes.

9 A It's tough to answer. The short answer would
10 probably be no.

11 Q So you've never seen a patient with pieces of
12 frayed mesh that are protruding out through the vagina?

13 MR. DIPOLA: Object to form. Asked and
14 answered.

15 THE WITNESS: Yes, I have, but I don't
16 know if I would describe those as frayed.

17 BY MR. FAES:

18 Q How would you describe it?

19 A Just as you did the second time around, a
20 piece of mesh that's being exposed to the vaginal wall.

21 Q Have you ever seen one of your patients with
22 mesh that was folded or wrinkled.

23 A I kind of put that into that curling
24 category. Whether it's curling or folded, it's hard to

1 distinguish, but yes, in essence I have seen patients
2 like that.

3 Q And when you've seen patients like that
4 you've treated them the same way as you did with a
5 sling that was roped or curled, correct?

6 A Correct.

7 Q And I think I forgot to ask, how do you
8 typically treat a patient who comes in with frayed mesh
9 as you defined it, mesh edges protruding out through
10 the vagina?

11 MR. DIPOLA: Again, object to form.

12 THE WITNESS: I personally would take
13 them to the operating room, get a better look at the
14 situation, and probably not only excise the part that's
15 coming through, but also any edges of the sling that
16 were adjacent, and then reconstruct the vaginal wall.

17 BY MR. FAES:

18 Q Doctor, in your experience can surgical mesh
19 shrink or contract and cause pain for a woman?

20 MR. DIPOLA: Object to form.

21 THE WITNESS: I believe that ones
22 tissues can shrink and contract as part of the healing
23 process. I'm not convinced that polypropylene or
24 slings can shrink and contract.

1 BY MR. FAES:

2 Q I think we're getting into semantics, but you
3 would agree that when the tissue contracts as part of
4 the healing process, it can encapsulate the mesh, and
5 the mesh can be shrunk along with the scar tissue,
6 correct?

7 MR. DIPOLA: Object to form.

8 THE WITNESS: I guess it's just hard to
9 define if the mesh is shrinking. The tissues are
10 contracting, because that's sort of a dynamic state.
11 I'm not sure the mesh is changing.

12 BY MR. FAES:

13 Q So you've never heard anything described in
14 the medical literature regarding mesh becoming
15 contracted or shrinking and entrapping nerves within
16 the interceeds of the mesh?

17 MR. DIPOLA: I'll object to form, asked
18 and answered, vague, assumes facts.

19 THE WITNESS: To your point it's just
20 hard to know whether it's the tissue around the mesh or
21 the mesh itself that's changing. I think it's more the
22 tissue.

23 BY MR. FAES:

24 Q Doctor, you testified earlier that you

1 believe you do about 20 surgical revisions or -- strike
2 that.

3 I think you testified earlier that you do
4 approximately 20 revisions of surgical mesh a year; is
5 that right?

6 A Correct.

7 Q Have you ever reported any of those revisions
8 or problems to Ethicon?

9 A Yes. I'm sure I have.

10 Q Have you ever reported any of those problems
11 to any of the other manufacturers, if it's a different
12 manufacturer?

13 A Yes.

14 Q Would you say it's your standard practice to
15 report those problems, or do you only do it on a
16 sporadic basis?

17 MR. DIPOLA: Object to form.

18 THE WITNESS: If I could identify which
19 sling it was, or product it was that was being used,
20 usually I would convey the information to the company
21 via my rep in most cases.

22 BY MR. FAES:

23 Q And how would you typically do that? Via
24 e-mail, or would you tell the rep verbally?

1 A Could be any one of the above.

2 Q Doctor, have you ever reported an adverse
3 event from a medical device to the FDA?

4 A No.

5 Q Doctor, in your experience completely
6 removing midurethral sling products, were you able to
7 completely remove all the mesh?

8 MR. DIPOLA: Object to form.

9 THE WITNESS: In some cases, yes.

10 BY MR. FAES:

11 Q Would you agree that there are cases where
12 it's impossible for the surgeon to be unable to remove
13 the entirety of the mesh safely?

14 MR. DIPOLA: Object to form.

15 THE WITNESS: There are some cases you
16 would be unable to remove the mesh entirely.

17 BY MR. FAES:

18 Q So you would agree that there are some cases
19 where the mesh will remain within the patient's body
20 forever?

21 A Part of it, yes.

22 Q Doctor, would you agree that it's challenging
23 to remove all of the mesh from a woman?

24 MR. DIPOLA: Object to form.

1 THE WITNESS: It certainly can be
2 challenging, yes.

3 BY MR. FAES:

4 Q Doctor, would you agree that the TVT mesh
5 produces a chronic inflammatory response that will
6 continue for as long as the mesh is within the
7 patient's body?

8 MR. DIPOLA: Object to form. Assumes
9 facts not in evidence. Hypothetical.

10 THE WITNESS: I can't say I agree with
11 that statement.

12 BY MR. FAES:

13 Q So you believe that the inflammatory response
14 stops at some point after the mesh is placed within the
15 body?

16 A Yes.

17 Q At what point do you believe that the
18 inflammatory response stops after the TVT mesh is
19 placed in the patient's body?

20 MR. DIPOLA: Form, vague.

21 THE WITNESS: I think it's hard to
22 answer specifically. I think it differs with different
23 individuals in different circumstances depending on how
24 much material was used. So I would say within the

1 first year.

2 BY MR. FAES:

3 Q Doctor, do you typically perform the --
4 strike that. I don't think I've asked this yet.

5 When is the last time that you recall
6 performing a TVT retropubic, and again, by that I mean
7 the TVT Classic device, when is the last time you
8 recall putting one of those in?

9 A Probably in the last year.

10 Q When you put the TVT retropubic device in, do
11 you typically do that under local or general
12 anesthesia?

13 A Usually it's either a spinal or general. In
14 my case not local.

15 Q Do you know which is more common for
16 physicians to put it in under local or general
17 anesthesia?

18 MR. DIPOLA: Object to the form.

19 THE WITNESS: I think it depends on the
20 individual's practice. I can only speak for myself.

21 BY MR. FAES:

22 Q Doctor, do you know what the pore size is of
23 the Prolene mesh in the TVT product?

24 A I don't know off the top of my head, no.

1 Q Have you ever heard that the pores -- strike
2 that.

3 Have you ever heard that if the pores in the
4 TVT mesh collapse, it can increase the risk of erosion
5 or bridging fibrosis?

6 MR. DIPOLA: Object to form. Assumes
7 facts not in evidence.

8 THE WITNESS: The idea of them
9 collapsing, I wouldn't say I've heard of that.

10 BY MR. FAES:

11 Q Do you know as you sit here today whether or
12 not the pores in the TVT mesh can collapse?

13 MR. DIPOLA: Same objection. Asked and
14 answered.

15 THE WITNESS: I do not believe they
16 collapse.

17 BY MR. FAES:

18 Q Would you agree that if the pores in a
19 surgical mesh are not large enough, there can be a risk
20 of increased infection?

21 A Yes.

22 Q Would you agree that if the pores in a
23 surgical mesh are not large enough, it can increase the
24 risk of erosion for the patient?

1 A Yes.

2 Q Would you agree that if the pores in a
3 surgical mesh are not large enough, there can be poor
4 tissue integration which can cause a wound healing
5 defect?

6 MR. DIPAOLO: Object to form. Assumes
7 facts not in evidence.

8 THE WITNESS: Yes.

9 BY MR. FAES:

10 Q Doctor, do you know what the weight of the
11 mesh in the TVT is?

12 A No.

13 Q Do you know what purpose the Prolene mesh
14 that's used in the TVT was originally developed or used
15 for?

16 A No.

17 MR. DIPAOLO: Objection to form.

18 BY MR. FAES:

19 Q Doctor, have you ever been employed by a
20 medical device company?

21 A No.

22 Q Now, I take it you have acted as a consultant
23 to various medical device and pharmaceutical companies,
24 correct?

1 A Correct.

2 Q You've been a consultant for American Medical
3 Systems?

4 A Yes.

5 Q Have you been a consultant for Astoria
6 Health, which is what American Medical Systems is
7 called now?

8 A Yes.

9 Q Have you been a consultant for Boston
10 Scientific, correct?

11 A Yes.

12 Q You've been a consultant for CR Bard?

13 A Yes.

14 Q You've been a consultant for Cook?

15 A Not that I recall.

16 Q You've been a consultant for Caldera?

17 A Not that I can -- no.

18 Q And you have been a consultant for Ethicon,
19 correct?

20 A Correct.

21 Q Do you recall when your consulting agreement
22 with Ethicon first began?

23 A I would have to guess. It's somewhere around
24 2003 or so, but I'm really not sure. Could be 2005.

1 Q Do you agree that you've been an advocate of
2 Ethicon mesh products?

3 MR. DIPOLA: Object to form.

4 THE WITNESS: Yes.

5 BY MR. FAES:

6 Q And you've consulted for a number of
7 pharmaceutical companies as well, right?

8 A Yes.

9 Q You've consulted for Allergan?

10 A Yes.

11 Q You've consulted for Astellas
12 Pharmaceuticals?

13 A Astellas? Astellas.

14 Q Astellas, yes. The aforementioned overactive
15 bladder drug that I can't pronounce.

16 A Yes.

17 Q You've acted as a consultant for Bayer?

18 A Yes, probably in the past.

19 Q You've acted as a consultant for, which
20 actually isn't a pharmaceutical company, but Medtronic
21 in the past?

22 A I'm not sure. I do not think I have.

23 Q Do you recall if you've ever received any
24 payments from Medtronic for attending any events?

1 MR. DIPOLA: Objection to form. Beyond
2 the scope.

3 BY MR. FAES:

4 Q Or anything like that for them?

5 A I do not believe so. And if it was, it was a
6 long time in the past.

7 Q So you don't believe you've received any
8 payments from Medtronic as recently as 2014?

9 A No.

10 Q Have you been a consultant for Neotract in
11 the past?

12 A Neotract. There again, I don't believe so.

13 Q Novartis?

14 A Yes.

15 Q Uroplasty?

16 A I don't think I've done any consulting work
17 for them, no.

18 Q Covidien?

19 A Maybe. If I did, it was a long time ago.

20 Q Intuitive Surgical?

21 A No.

22 Q Is there any other medical device or
23 pharmaceutical companies that you've done consulting
24 work for in the past that you can think of as you sit

1 here today?

2 A Sure.

3 Q And what are those?

4 A Pfizer, Allergan. I'm sure there are others.

5 Q Do you know what pharmaceutical and medical
6 device companies you're currently consulting for?

7 A Currently? I would just say Boston
8 Scientific.

9 Q Just Boston Scientific?

10 A Correct.

11 Q And Ethicon as a litigation consultant,
12 correct?

13 A Correct.

14 Q When did your relationship with Astellas
15 Pharmaceuticals end?

16 A Oh, I'm sorry. I still have a relationship
17 with them. I thought you meant did I -- yes, I still
18 have a relationship with Astellas.

19 Q Let me reask the question, because I'm not
20 sure you understood the last question.

21 Are there any other pharmaceutical companies
22 that you're currently consulting for?

23 A Astellas.

24 Q Just Astellas?

1 A Correct.

2 Q Doctor, would you agree that you first became
3 a paid consultant for Ethicon in 2005?

4 MR. DIPOLA: Objection to form. Asked
5 and answered.

6 THE WITNESS: I think that was the time
7 frame, but I'm not sure.

8 BY MR. FAES:

9 Q When were you first contacted to give your
10 opinions in this case?

11 A In this case, I would say in the last six
12 months.

13 Q And prior to that do you recall when the last
14 time was that you had a consulting relationship with
15 Ethicon?

16 A I would say probably some time around the
17 last five years, maybe. Five years ago, put it that
18 way.

19 (Plaintiff's Exhibit 9, E-mail dated
20 7/7/04 Bates 638006 through 008: Marked for
21 Identification.)

22 BY MR. FAES:

23 Q Doctor, I'm going to hand you what's been
24 marked as Exhibit number 9.

1 MR. DIPOLA: You don't have any copies
2 of these, do you?

3 MR. FAES: I don't on this one.

4 BY MR. FAES:

5 Q And I'm actually going to ask you questions
6 about the second page. This is an e-mail dated
7 July 2004. Do you see that?

8 A Yes.

9 Q And if you go to the second page it's an
10 e-mail to you from Ettore Carino at Ethicon. Do you
11 see that?

12 A Sure.

13 Q I want to have you go down to, I think it's
14 the sixth paragraph starting with, Third, do you see
15 that where it says, Third, armed with the context of
16 what Gynecare is doing and why sponsor you to visit
17 with Dr. De Laval in Belgium. We are sending a handful
18 of surgeons to spend time with Dr. De Laval to learn,
19 challenge, brainstorm on how what's been uncovered, and
20 the mechanisms of action, and where we can take it to
21 the next level. Do you see that?

22 A I do.

23 Q Do you recall that in July of 2004 Ethicon
24 offered to send you to Belgium all expenses paid to

1 train with Dr. De Laval on the TVT-O device?

2 MR. DIPOLA: Object to form. Assumes
3 facts.

4 THE WITNESS: I do. I do remember
5 meeting with Dr. De Laval right around that time, yes.

6 BY MR. FAES:

7 Q So you did actually make this trip to Belgium
8 to see Dr. De Laval?

9 A I did.

10 Q And Ethicon, I take it, paid for your flight,
11 and your travel expenses, and your hotel while you were
12 there, correct?

13 A Correct.

14 Q Do you recall any other instances where
15 Ethicon paid for your travel internationally to either
16 train or be a trainer or speaker for them?

17 A I'm sure there are other occasions, yes.

18 Q Do you recall if you were sent to Paris for a
19 TVT Secure meeting?

20 A May have been. It's a long time ago. I
21 don't remember specifics. I did a lot of meetings,
22 hard to know.

23 Q Do you recall if Ethicon sent you to New
24 Zealand to do lectures or talks on the TVT Secure

1 product?

2 MR. DIPOLA: Object to form.

3 THE WITNESS: There again, it's a long
4 time ago, but I've definitely been to New Zealand for a
5 meeting, so I wouldn't be surprised if I was there for
6 them as well.

7 BY MR. FAES:

8 Q Do you recall how many time you've been to
9 New Zealand? Has it been more than once? I would
10 expect New Zealand to be a pretty memorable experience.

11 A There have been a couple meetings in
12 Australia. So when you're in Australia, you tend to go
13 to New Zealand. So, yes, I've been there before, and I
14 would not be surprised if I've done something with
15 Gynecare while I was there.

16 Q So I take it you wouldn't be surprised if
17 Ethicon paid for your travel and expenses while you
18 went to New Zealand and/or Australia to give talks or
19 lectures or training regarding their products, correct?

20 A Correct.

21 (Plaintiff's Exhibit 10, Consulting
22 Agreement Bates 16261092 through 1096: Marked for
23 Identification.)

24

1 BY MR. FAES:

2 Q Doctor, I'm going to hand you what's been
3 marked as Exhibit number 10 to your deposition. I'm
4 really only going to ask you about the date on the
5 front and something that's on page 2.

6 A Yes.

7 Q This appears to be a contract between you and
8 Ethicon dated January 18, 2005. Do you see that?

9 A I do.

10 Q If you look on page 2, item number 7, it
11 says, Ethicon hereby invites and Consultant accepts
12 invitation by Ethicon for participation in the 2005
13 Incontinence and Pelvic Floor Summit in Salt Lake City,
14 Utah. Do you see that?

15 A Yes.

16 Q And it states under Section 8 that \$500 will
17 be paid for consultant's participation.

18 A Yes.

19 Q So you would agree that at least as of 2005
20 you were first approached by Ethicon to be a consultant
21 for one of their products, correct?

22 A Yes.

23

24

1 (Plaintiff's Exhibit 11, Letter dated
2 2/06 Bates 888751 through 756: Marked for
3 Identification.)

4 BY MR. FAES:

5 Q I'm going to hand you what's been marked as
6 Exhibit Number 11 to your deposition. And this is a
7 contract between you and Ethicon dated February
8 of 2006. Do you see that?

9 A I do.

10 Q If you turn to page 2 under section C, you
11 see it states, Any work performed in connection with
12 his consultancy will not be published in written or
13 oral form without the permission of Ethicon. When
14 publication of results is agreed to by Ethicon,
15 consultant agrees to submit to Ethicon the material
16 sought to be published or a draft proposal oral
17 presentations disclosing or discussing the results of
18 work performed under the agreement at least four months
19 prior to the submission of material from publication or
20 oral presentation. Do you see that?

21 A I do.

22 Q Do you recall at this time you were an
23 investigator for Ethicon for a TVT-O clinical study?

24 A I've done a lot of studies for different

1 products, so that certainly could have been the reason
2 for this contract.

3 Q Would it appear that according to this
4 contract prior to publishing any work from any studies
5 it would have to be approved by Ethicon prior to being
6 published?

7 MR. DIPAOLO: Object.

8 BY MR. FAES:

9 Q Is that your understanding of this agreement?

10 MR. DIPAOLO: Misstates.

11 THE WITNESS: It's pretty standard
12 language to most studies that you do where they want to
13 see the data before it's published.

14 BY MR. FAES:

15 Q So under the terms of this agreement, if
16 there was data that was not favorable to a product that
17 you were working on, Ethicon could tell you that, no,
18 we don't want you to publish that data; is that
19 correct?

20 MR. DIPAOLO: Objection. Totally
21 misstates facts.

22 THE WITNESS: Yes, I don't have that.

23 BY MR. FAES:

24 Q You don't have that?

1 A It never came up, never became an issue. If
2 we ever had data we wanted to publish, it wasn't as if
3 anybody restricted us from publishing it.

4 Q If you turn to page 3 of the agreement under
5 Section 8, it states that in consideration of your
6 acceptance of this consulting agreement, you'll be paid
7 \$3,000 a day; is that correct?

8 A It says that, yes.

9 Q And it also says that under no circumstances
10 will their total obligations under this agreement
11 exceed \$15,000 without express written approval,
12 correct?

13 A It says that, yes.

14 Q So this particular contract is for up to
15 \$15,000; is that correct?

16 A Correct.

17 (Plaintiff's Exhibit 12, Master
18 Consulting Agreement dated 8/20/07 Bates 02245633
19 through 643: Marked for Identification.)

20 BY MR. FAES:

21 Q Doctor, I'm going to hand you what's been
22 marked as Exhibit number 12 to your deposition.

23 I'm just going to hand you that, and this is
24 a consulting agreement between you and Ethicon dated

1 August 20, 2007.

2 A Okay.

3 Q Do you see that?

4 A I do.

5 Q If you turn to the third page under paragraph
6 12, you see where it says in about the middle of the
7 paragraph, You shall not make any representation
8 relating to company's products or to company's clinical
9 outcomes unless such representations have been reviewed
10 and approved in advance by the company. Do you see
11 that?

12 A I do see that.

13 Q Is that your understanding of one of the
14 terms and conditions that you agreed to when you became
15 a consultant for Ethicon?

16 A It never came up during the consultancyship.
17 I never specifically remember this phrasing of this
18 issue.

19 Q But you would agree that at least according
20 to this contract that you were not supposed to make any
21 representation relating to the company's products or
22 clinical outcomes unless they had been reviewed and
23 approved in advance by the company?

24 A Well, it says that they need to be discussed

1 with the company.

2 Q You believe that this says they have to be
3 discussed, not that they have to be reviewed and
4 approved in advance by the company?

5 A Again, it never really became an issue with
6 anything we worked on, so I never really scrutinized
7 it. So I guess it's subject to your interpretation.

8 Q So is it your testimony that you didn't have
9 an understanding while you were a consultant for
10 Ethicon that any materials that you used during
11 lectures or presentations or physician talks or dinners
12 didn't need to be reviewed and approved in advance by
13 the company?

14 MR. DIPOLA: Object to form.

15 THE WITNESS: There were plenty of
16 things we used that weren't approved or they didn't see
17 ahead of time in lectures or in different
18 presentations.

19 (Plaintiff's Exhibit 13, Master
20 Consulting Agreement dated 3/1/08 Bates 00369005
21 through 9015: Marked for Identification.)

22 BY MR. FAES:

23 Q Doctor, I'm going to hand you what's been
24 marked as Exhibit number 13 to your deposition, and

1 this is a contract between you and Ethicon dated
2 March 1st of 2008. Do you see that?

3 A I do.

4 Q I just want to direct your attention to --
5 unfortunately there's no page number, but the Bates
6 number at the bottom is ending in 9011, and it's listed
7 as Exhibit A, services and fees.

8 A Okay. Got it.

9 Q You see there under section 3 it states that
10 you're to be paid \$375 an hour and up to \$3,000 per
11 eight-hour day. Do you see that?

12 A I do.

13 Q Plus reasonable out-of-pocket expenses?

14 A Yes.

15 Q Is that your understanding of what your
16 agreement was regarding fees with Ethicon at this time
17 in 2008?

18 A Yes.

19 Q If you turn to the following page under
20 Section B. Did you find it, Doctor? It says that the
21 parties agree that compensation paid to the consultant
22 shall not exceed 72,000 per year except has to be
23 mutually agreed in writing by the parties. Do you see
24 that?

1 A That's on which page?

2 Q It's ending in 9012. It is the very last
3 paragraph.

4 A Yes, I do see that now.

5 Q So can you agree that this contract dated as
6 of March 2008 is for up to \$72,000 a year?

7 A They seem to have a cap, yes, on the actual
8 maximum compensation.

9 (Plaintiff's Exhibit 14, Master
10 Consulting Agreement dated 3/1/09 Bates 369362 through
11 370: Marked for Identification.)

12 BY MR. FAES:

13 Q Doctor, I'm going to hand you what's been
14 marked as Exhibit 14 to your deposition. I'm really
15 only going to ask you about one thing on it. I'm going
16 to turn back the corner here just to save time since
17 I've only got three hours to talk to you here.

18 A Okay.

19 Q This is a contract dated March 1, 2009,
20 between you and Ethicon. Do you see that?

21 A I do.

22 Q If you turn to the page that I tabbed for you
23 ending in 9369 at the very bottom, it states that the
24 compensation on this contract shall not exceed \$78,000

1 per year.

2 A Yes.

3 Q Do you see that?

4 A I do see that.

5 Q So again, you would agree that the maximum
6 amount on this contract in 2009 was \$78,000, correct?

7 A Yes.

8 Q Do you recall how much you were paid by
9 Ethicon in 2010 for consulting work?

10 A I do not recall.

11 Q Do you recall if it was in excess of \$104,000
12 a year?

13 A I don't recall.

14 Q But as you sit here today, do you have
15 anything to offer one way or the other to dispute the
16 fact that you were paid \$104,000?

17 A I really have no idea.

18 Q Do you recall how much you were paid by
19 Ethicon in 2011 as a consultant?

20 A There again, I really don't know.

21 Q Do you know if it was in excess of \$105,000
22 that year as a consultant for Ethicon?

23 A I have no idea.

24 Q Do you recall if you were a consultant for

1 Ethicon in 2011?

2 A I may have been.

3 Q Do you recall if you were a consultant for
4 Ethicon in 2010?

5 A There again, most likely, yes.

6 Q Can we agree that based on the documents that
7 we've gone through today you've been a consultant for
8 Ethicon at least from 2005 through 2011?

9 A I've seen documents through 2009. So I can
10 agree with 2005 to 2009.

11 MR. FAES: Is it okay if we take a quick
12 break? We've been going about an hour and a half.

13 (Recess: 5:51 p.m. to 5:56 p.m.)

14 BY MR. FAES:

15 Q Doctor, we're back on the record after a
16 short break. Are you ready to proceed?

17 A I am.

18 (Plaintiff's Exhibit 15, Consulting
19 Agreement Requisition Form Bates 08706296 through 306:
20 Marked for Identification.)

21 BY MR. FAES:

22 Q Doctor, I'm going to hand you Exhibit 15 to
23 your deposition. Do you recognize this?

24 A I do.

1 Q This appears to be a consulting agreement
2 requisition form dated between May 20 of 2010 and
3 April 19 of 2011. Do you see that?

4 A I do.

5 Q And actually attached to that, if you go two
6 pages in, is the agreement dated May 20, 2010? Do you
7 see that?

8 A I do.

9 Q Now, based on all the documents that we've
10 gone through today, would you agree that you've been a
11 consultant for Ethicon from at least 2005 through 2011?

12 A Yes.

13 Q Doctor, would you agree that during the at
14 least seven years that you've been a paid consultant
15 for Ethicon your contract amounts, or at least the
16 amount that you could be paid, have been in excess of
17 \$350,000?

18 MR. DIPOLA: Object to form.

19 THE WITNESS: That seems to be the
20 maximum that they would pay, but the maximums are
21 usually never reached. That does seem like a very high
22 number, but I don't remember exactly how much I
23 received each year.

24

1 BY MR. FAES:

2 Q Do you recall if your maximum was not only
3 reached but exceeded in 2010?

4 A I don't recall that.

5 Q Is it possible that there were years where
6 your maximum contract amount was actually exceeded by
7 written agreement?

8 A I don't recall.

9 Q Do you recall if your maximum contract amount
10 was exceeded in 2011?

11 A I don't recall.

12 Q Do you recall as you sit here today how much
13 money you've been paid as a consultant for Ethicon
14 prior to being retained in this litigation?

15 A I just don't recall.

16 Q Do you know if it's more or less than a half
17 million dollars?

18 A I would consider it to be less.

19 Q Do you know if it's more or less than a
20 quarter million dollars?

21 A I would consider it to be less, but I don't
22 really recall.

23 Q If you go back to Exhibit number 1 to your
24 deposition, which is the notice of deposition in the

1 case. Did you know that there was a section in that
2 notice that specifically asked you to produce 1099s
3 from Ethicon for the prior five years?

4 A I don't have those.

5 Q Did you look for those at all?

6 A I did not.

7 Q Did you look for or do you have any of your
8 prior 1099s from Ethicon during your time as working as
9 a consultant for them?

10 MR. DIPOLA: Objection to form.

11 THE WITNESS: I have to look.

12 BY MR. FAES:

13 Q Would you agree that if you had those 1099s
14 and brought them with you here today we could confirm
15 the amounts that you were actually paid by Ethicon for
16 the years 2005 through 2011?

17 MR. DIPOLA: Object to form.

18 Argumentative.

19 THE WITNESS: If I had them, yes. Yes,
20 if I had them you would be able to confirm it.

21 BY MR. FAES:

22 Q Doctor, have you promoted the Abbrevio product
23 for Ethicon before?

24 A I'm sure I did.

1 Q Have you promoted the Exact product for
2 Ethicon before?

3 A I'm sure, yes.

4 Q Have you promoted the TVT and TVT-O product
5 for Ethicon before?

6 A Yes.

7 Q TVT Secure?

8 A Yes.

9 Q Prosima?

10 A No.

11 Q You've never promoted the Prosima product
12 before Ethicon before?

13 A No.

14 MR. DIPOLA: Objection.

15 BY MR. FAES:

16 Q The Prolift?

17 A Yes.

18 Q Prolift+M?

19 A Yes.

20 Q Gynemesh PS?

21 A Not that I recall.

22 Q What about the Ethicon Artisyn Mesh?

23 A Not that I recall.

24 Q Have you ever worked on -- strike that.

1 Have you ever promoted the Ethicon Dermabond
2 product before?

3 A No.

4 Q What about the Ethicon Monitor?

5 A No. Not that I recall.

6 Q Would you agree that you've traveled to Miami
7 before for Ethicon to promote one or more of their
8 pelvic mesh products?

9 MR. DIPOLA: Object to form.

10 THE WITNESS: I can't say I recall
11 specifically doing that.

12 BY MR. FAES:

13 Q Do you have any reason to dispute it one way
14 or the other, or you just don't recall?

15 A I don't recall. I definitely traveled for
16 Ethicon. Was it Miami, I don't know.

17 Q Do you recall if you've ever traveled to
18 San Francisco for Ethicon to promote pelvic mesh
19 products?

20 A Don't recall.

21 Q Pittsburgh?

22 A Again, I don't recall specifically.

23 Q Salt Lake City?

24 A That one you showed me a paper on Salt Lake,

1 so I do remember that.

2 Q Have you ever traveled to Short Hills, New
3 Jersey as part of your consulting work with Ethicon?

4 A I'm sure I did.

5 Q Have you ever traveled to Baltimore as part
6 of your consulting work with Ethicon?

7 A Probably, yes.

8 Q Have you ever traveled to Buffalo, New York
9 as part of your consulting work with Ethicon?

10 A I don't specifically remember, but probably.

11 Q Have you ever traveled to Sonoma, California
12 as part of your consulting work with Ethicon?

13 A Yes.

14 Q Dallas, Texas?

15 A Yes.

16 Q Chicago?

17 A Don't recall.

18 Q Nashville?

19 A I don't recall.

20 MR. DIPOLA: Are you going to name
21 every city in the country?

22 MR. FAES: No, just certain ones.

23 BY MR. FAES:

24 Q How about Pittsburgh, do you recall that? I

1 may have already asked that.

2 A I'm not sure.

3 Q Do you know how much you've been paid as a
4 consultant by American Medical Systems during the
5 course of your consulting contract with them?

6 A There again, I'm not sure.

7 Q What about Boston Scientific?

8 A Not sure.

9 Q Would it be fair to say that over the course
10 of your entire medical career you've been paid at least
11 half a million dollars in consulting fees by
12 pharmaceutical and medical device companies?

13 MR. DIPOLA: Object to form.

14 THE WITNESS: Sounds high. I'm not
15 sure.

16 BY MR. FAES:

17 Q You're not sure?

18 A Not sure.

19 Q Would it be fair to say that you've been paid
20 more than a million dollars by pharmaceutical and
21 medical device companies for consulting work during the
22 course of your medical career?

23 A Sounds extremely high, and there again, I
24 just don't know the numbers.

1 Q Would you agree that you are still a paid
2 consultant for Ethicon today?

3 A In this type of setting, yes.

4 Q So outside of litigation you're not a paid
5 consultant for Ethicon?

6 A Correct.

7 Q But you would consider the work that you're
8 doing for Ethicon today as paid consulting work,
9 correct?

10 A I wouldn't necessarily, but I thought you
11 referenced that it was.

12 Q Now, the contracts that you've had in the
13 past with Ethicon you were considered a preceptor for
14 Ethicon; is that correct?

15 A Correct, I've been a preceptor.

16 Q What is your understanding of what a
17 preceptor is?

18 A Someone who has knowledge of a certain
19 surgical procedure and can share that knowledge with
20 those who do not have that knowledge.

21 Q As part of your duties as a preceptor one of
22 your roles was to give lectures to doctors regarding
23 the products manufactured by Ethicon, correct?

24 A Correct.

1 Q Can we agree that during the years between
2 2005 and 2011 your responsibilities to Ethicon and
3 travel around the nation and internationally increased
4 over the years?

5 MR. DIPOLA: Object to form.

6 THE WITNESS: I think it just depended
7 on the year and what was being used. I don't think
8 that chronology necessarily actually increased over
9 time.

10 BY MR. FAES:

11 Q Well, we saw that in 2005, your first
12 contract with Ethicon was for \$500 for a pelvic floor
13 summit in Salt Lake City, right?

14 A Well, that was one particular day, I think.
15 If I remember that conference, I gave a lecture at it,
16 it was a pelvic floor summit, different than a
17 consultantship that would go on to teach products, or
18 teach the different --

19 Q And then the following year in 2006 you had a
20 contract worth \$15,000?

21 MR. DIPOLA: Objection to form.
22 Mischaracterizes.

23 THE WITNESS: I think the last contract
24 had a maximum of 10,000 on it. The one you showed me

1 from 2010, so that seems to be less.

2 BY MR. FAES:

3 Q Would you agree that between 2006 and 2008
4 your contract went from a maximum of 15,000 to 72,000,
5 correct?

6 A Those numbers are correct.

7 Q And then from 2008 to 2009 your contract went
8 from 72,000 to 78,000, correct?

9 A Correct.

10 Q And as you sit here today, you don't recall
11 how much you were paid in 2010 by Ethicon as a
12 consultant, correct?

13 MR. DIPOLA: Asked and answered.

14 THE WITNESS: Correct.

15 BY MR. FAES:

16 Q Doctor, do you have a copy of all your
17 consulting agreements with Ethicon somewhere?

18 A Probably not.

19 (Plaintiff's Exhibit 16, E-mail dated
20 7/1/10 Bates 08956995 through 996: Marked for
21 Identification.)

22 BY MR. FAES:

23 Q Doctor, I'm going to hand you what's been
24 marked as Exhibit number 16 to your deposition, and

1 this is an e-mail dated July 1st of 2010, and the part
2 I want to ask you about is down at the bottom on the
3 first page where it says, Hi all. I spoke with Matt
4 earlier, and I have great news. We are good to go with
5 inviting two surgeons to the Competitive War Games
6 meeting on July 27th. Here is the list in rank order
7 of surgeons we would look to invite.

8 And it looks like you're the second one down,
9 Scott Serels, although your name is spelled
10 incorrectly. Do you see that?

11 A I do.

12 Q Do you recall being invited to this
13 Competitive War Games around this time?

14 A I don't remember the exact name, but I do
15 remember going to something with that group of people.

16 Q Do you recall what the Competitive War Games
17 entailed?

18 A Not 100 percent, no. I don't remember it
19 being referred to as that topic, but I think there were
20 times where we would discuss what products we use, and
21 why we believe in them, and where the benefits and the
22 flaws were on certain things, but I don't remember this
23 exact meeting.

24 Q Do you recall if at this time in 2010 you

1 were still acting as a consultant to Boston Scientific?

2 A Well, I'm not sure, but I may have been.

3 Q Do you recall at this time in 2010 if you
4 were still acting as the consultant to American Medical
5 Systems?

6 A I may have been.

7 Q Do you recall if one of the purposes of this
8 meeting was to discuss strategies to distinguish
9 Ethicon's products from their competitors products,
10 such as AMS and Boston Scientific?

11 MR. DIPOLA: Object to form. Assumes
12 facts not in evidence.

13 THE WITNESS: I don't really recall this
14 meeting in that kind of detail.

15 (Plaintiff's Exhibit 17, E-mail dated
16 8/30/06 Bates 03013633 through 634: Marked for
17 Identification.)

18 (Plaintiff's Exhibit 18, Letter dated
19 6/29/06 Bates 03005774 through 775: Marked for
20 Identification.)

21 BY MR. FAES:

22 Q Doctor, I'm going to hand you two exhibits
23 what's been marked as Exhibits 17 and 18 to your
24 deposition, and I'm going to ask you about Exhibit

1 number 17 first.

2 If you can turn to the second page. These
3 are kind of in reverse order where the first e-mail
4 starts on the second page, and it appears to be a draft
5 e-mail to you that was not sent to you from a Judy
6 Gauld at Ethicon, and it says, Dear Dr. Serels,
7 following the recent monitoring visits performed at
8 your site for the above study, I understand there are a
9 number of areas of concern regarding the consenting
10 process, documentation of patient visits, device
11 accountability, and patient follow-up. As you will
12 appreciate, we must ensure that all aspects of our
13 studies are run to the highest professional standards
14 in order to protect patient welfare, rights and safety.
15 I would therefore be grateful if you could ensure that
16 all necessary corrective actions are put in place to
17 address those protocol deviations already identified
18 and minimize the risk of any repetition. Do you see
19 that?

20 A Uh-huh.

21 Q And you see the subject line is Gynecare TVT
22 obturator protocol 300-04-004?

23 A Uh-huh.

24 Q Was this a TVT-O study that you were involved

1 in as a clinical investigator for Ethicon?

2 A Yes.

3 Q Do you recall if you were being reimbursed
4 either in the form of a grant or other payment for this
5 study?

6 A I don't recall the specific financials.

7 Q Is it typical for someone like yourself who
8 participates as an investigator in a clinical study to
9 be reimbursed for their expenses and time in conducting
10 such a study?

11 MR. DIPOLA: Objection to form.

12 THE WITNESS: Yes.

13 BY MR. FAES:

14 Q Do you recall at this time in 2006 that there
15 were protocol deviations in this study from your
16 particular site?

17 A I don't recall, but it's certainly possible.
18 Little things come up with studies that need to be fine
19 tuned.

20 Q Would you agree that it's important to ensure
21 that all aspects of studies are run to the highest
22 professional standards in order to protect patient
23 welfare, rights and safety?

24 A A hundred percent I agree with that.

1 Q If you turn to the first page, again, going
2 in reverse order, this is actually an e-mail from Judy
3 Gauld to David Robinson, and you know David Robinson,
4 correct?

5 A I do.

6 Q And it explains the passage we just read
7 earlier, it says, Dave, here is some suggested wording
8 for Dr. Serels, Re, issues that we have had with him
9 for the TVT-O study. This letter can either come from
10 you, or if it would be easier from a relationship
11 management point of view, I'm happy to send from here.
12 Do you see that?

13 A I do.

14 Q And further up it seems to indicate from
15 David Robinson, I think the letter is fine, but since
16 he is a personal friend, it would be a great help if it
17 was signed by you instead of me. We can play good cop
18 bad cop, but this time you have to be the bad cop. Do
19 you see that?

20 A I do, yes.

21 Q And then if you look at Exhibit number 18,
22 this is a letter dated June 29, 2005, addressed to you?

23 A Yes.

24 Q Regarding the TVT obturator protocol?

1 A Yes.

2 Q Do you recall if you received this document?

3 A Do I recall receiving it back in 2005?

4 Q Yes.

5 A Oh, I don't remember.

6 Q Do you have any reason to dispute, as you sit
7 here today, that you received this document?

8 A No.

9 MR. DIPOLA: Object to form.

10 BY MR. FAES:

11 Q If you look down at the bottom of the first
12 page it states, The following items were discussed with
13 you and Teri Jacoby regarding your site's continued
14 participation in the study, and the second bullet point
15 says, You or Lori will need to answer all medical
16 questions the patient has regarding the procedures. Do
17 you see that?

18 A I do.

19 Q Do you recall who Lori is? Was that someone
20 in your office in 2005?

21 A Yes.

22 Q Do you recall there being an issue that the
23 auditor found that either you or your staff was not
24 answering all the medical questions the patient had

1 regarding the study procedures?

2 A I don't recall.

3 Q If you turn to the second page, do you see
4 where it says, Please follow up on the action items
5 listed below.

6 A Uh-huh.

7 Q And there's a fourth bullet point that says,
8 A note to file will be signed documenting the
9 consenting process for the five patients enrolled into
10 the study, and also noting that you signed the IC on a
11 later date, not the date that the IC was obtained. Do
12 you see that?

13 A Okay.

14 Q And IC, I assume, stands for informed
15 consent?

16 A Yes.

17 Q Do you recall there being an issue with the
18 study where informed consents were signed on a later
19 date and not the date that the informed consent was
20 actually received?

21 A I don't recall.

22 Q Do you recall if that was considered a
23 protocol deviation?

24 A I don't recall.

1 Q Do you recall how many patients you
2 ultimately enrolled for this particular study?

3 A I really don't recall.

4 Q Do you recall whether or not you ever
5 actually treated patients as a part of this study, or
6 whether they became part of the final study report?

7 A It's a long time ago. I don't remember.

8 Q Do you remember whether or not all of your
9 patients decided to quit the study and decided not to
10 go forward with it before any of the surgeries were
11 actually performed?

12 A No idea.

13 (Plaintiff's Exhibit 19, E-mail dated
14 3/16/08 Bates 00064050: Marked for Identification.)

15 BY MR. FAES:

16 Q I'm going to hand you what's been marked as
17 Exhibit number 19, and this is an e-mail dated
18 March 16, 2008, and I really only have one question
19 about this. If you look at the second to last sentence
20 it says, In fact, Pat Nevar has told me that Scott
21 Serels is not the easiest to work with in regards to
22 collection of critical data, so we may need to look
23 into adding another doctor from your region. Do you
24 see that?

1 A I do.

2 Q Do you ever recall being told by anyone at
3 Ethicon that you are not the easiest to work with in
4 regards to collection of clinical data?

5 A I don't recall.

6 Q Do you know if the fact that Ethicon believed
7 that you were not the easiest to work with in regards
8 to collection of clinical data was in part due to the
9 difficulties you experienced during the TVT-O study
10 that we discussed earlier?

11 MR. DIPOLA: Objection to form.

12 THE WITNESS: I don't recall. It was a
13 long time ago.

14 BY MR. FAES:

15 Q This e-mail here is actually discussing
16 potentially using you as a clinical investigator for
17 the Prosima device. Do you see that?

18 A Yes, I never used the Prosima device.

19 Q Do you recall ever being approached by
20 Ethicon regarding whether you wanted to be a clinical
21 investigator regarding the Prosima device?

22 A Don't recall. I never used the device.

23 Q Do you recall ever being asked for feedback
24 on the Prosima device or its prototype?

1 A Yes.

2 (Plaintiff's Exhibit 20, Project Mint
3 Document Bates 12922252: Marked for Identification.)

4 BY MR. FAES:

5 Q I'm going to hand you what's been marked as
6 Exhibit Number 20 to your deposition. Do you see at
7 the top this appears to be a fax from you dated July 6
8 of 2006?

9 A Yes.

10 Q And you see that you actually signed and
11 dated this at the bottom dated July 6 of 2006. Do you
12 see that?

13 A I do.

14 Q Do you recall that Project Mint is actually
15 discussing the Prosima device?

16 A I don't remember Mint being -- I don't
17 remember that specifically.

18 Q I'll represent to you that the Mint is the
19 development name for what ultimately became the Prosima
20 device, okay, so assume that to be true for the
21 purposes of the question.

22 A Okay.

23 Q Now, this appears to be a form that Ethicon
24 asked you for feedback on regarding the Prosima

1 product, and asked you to rank user needs on a scale
2 from zero to five, five being the highest importance
3 and zero being not needed. Do you see that?

4 A I do.

5 Q Do you agree with that?

6 A Yes.

7 Q Do you recall that the Prosima device
8 actually uses polypropylene mesh?

9 A I do.

10 Q Do you know that the Prosima device actually
11 uses the same polypropylene raw material that's used in
12 the TVT?

13 MR. DIPOLA: Object to form.

14 THE WITNESS: Sure. I know it's
15 polypropylene mesh, yes.

16 BY MR. FAES:

17 Q Now, you rated a repair system that enables a
18 standardized procedure to be of the highest importance
19 for the Prosima device, correct?

20 A Yes.

21 Q Would you agree that having a repair system
22 that enables a standardized procedure would also be of
23 the highest importance for the TVT product?

24 A Yes.

1 Q You rated, System components should be easily
2 placed and removed, as being of the highest importance
3 for the Prosima. Do you see that?

4 A I do.

5 Q Would you agree that having system components
6 that are easily placed and removed would also be of the
7 highest importance for the TVT product?

8 A Yes.

9 Q You rated that system components of the
10 Prosima should be well tolerated by the patient to be
11 of the highest importance. Do you see that?

12 A Yes.

13 Q Would you agree that having system components
14 that are well tolerated by the patient are also the
15 highest importance for the TVT product?

16 A Yes.

17 Q You stated that having a procedure that is
18 designed to avoid unintended trauma to be of the
19 highest importance for the Prosima product. Do you see
20 that?

21 A I do.

22 Q Would you also agree that that is of the
23 highest importance for the TVT product?

24 A Yes.

1 Q Now, I also note that you actually wrote in
2 three things yourself here under other. Do you see
3 that?

4 A Yes.

5 Q And one of the things that you wrote in was
6 that there should be a system with a minimal
7 recurrence. I assume you mean recurrence rate,
8 correct?

9 A Uh-huh.

10 Q And you rated that to be of the highest
11 importance, correct?

12 A Correct.

13 Q Would that also be true for the TVT system,
14 that it would be important to design it with a -- a
15 system for the TVT that has a minimal chance of
16 recurrence?

17 A Yes.

18 Q Do you know whether that was a user need that
19 was assessed when the TVT device was originally
20 designed in 1997?

21 MR. DIPOLA: Object to form.

22 THE WITNESS: I don't know that.

23 BY MR. FAES:

24 Q You also wrote in that the Prosima device

1 should be a system with minimal chance for
2 complications, and you rated that of the highest
3 importance. Do you see that?

4 A I do.

5 Q Would you agree that that is also a user need
6 for the TVT?

7 A Yes.

8 Q And that that is of the highest importance?

9 A Yes.

10 Q Do you know whether that particular user need
11 was assessed when the TVT device was originally
12 designed in 1997?

13 MR. DIPOLA: Object to form.

14 THE WITNESS: I'm not sure.

15 BY MR. FAES:

16 Q The two user needs that we discussed that you
17 just wrote in on this form, did you find it odd at all
18 that Ethicon didn't already have those as user needs
19 when they were asking you questions about needs for the
20 Prosima device?

21 MR. DIPOLA: Object to form.

22 THE WITNESS: No.

23 BY MR. FAES:

24 Q Would you agree that those are user needs

1 that should be assessed when designing a new medical
2 device?

3 MR. DIPOLA: Same objection.

4 THE WITNESS: Yes, I would agree with
5 that.

6 (Plaintiff's Exhibit 21, E-mail dated
7 5/27/09 Bates 07633427 through 430: Marked for
8 Identification.)

9 BY MR. FAES:

10 Q Doctor, I'm going to hand you what's been
11 marked as Exhibit Number 21 to your deposition. I'll
12 give you a second to review that. This is an e-mail
13 dated May 27th of 2009.

14 A Okay.

15 Q And actually, I'm only going to ask you about
16 the very last page of the document, which is the first
17 e-mail in the chain, and that's dated May 26th of 2009.

18 A What page is that?

19 Q It's the second to the last page. And you
20 see it's an e-mail dated May 26, 2009, and it states,
21 Pelvic floor marketing team. For a call Thursday the
22 following has been identified by the PEMs for each
23 region for executing the Prolift+M forms. They avoided
24 some of the usual lead faculty as we discussed last

1 week. On the call we can discuss the list and the
2 steps to prepare each of them to present as faculty.
3 Do you see that?

4 A Yes.

5 Q And under the northeast it has your name, and
6 by that it says, Lack of case experience, but has done
7 +M lectures and is credible with urologists. Do you
8 see that?

9 A I do.

10 Q So would you agree that you were -- you
11 actually gave lectures on the Prolift+M?

12 A I did.

13 Q Do you believe that you had a lack of case
14 experience when you were giving lectures on the
15 Prolift+M?

16 A No.

17 Q Did you know that Ethicon believed that you
18 had a lack of case experience to be giving lectures on
19 the Prolift+M when they asked you to give those
20 lectures?

21 MR. DIPOLA: Objection to form.
22 Mischaracterizes.

23 THE WITNESS: +M was just a difference
24 in the type of mesh they were using, not the

1 application of the mesh. So perhaps I didn't use as
2 much of that type of mesh before, but the procedure I
3 was quite familiar with.

4 BY MR. FAES:

5 Q Well, my question was actually a little
6 different than that.

7 A Yes.

8 Q My question was, did you know at the time
9 that you were giving +M lectures that Ethicon believed
10 that you lacked case experience with the +M, but
11 decided to have you do them anyway because you were
12 credible with urologists?

13 MR. DIPOLA: Object to form.

14 THE WITNESS: I wasn't aware of that.

15 BY MR. FAES:

16 Q Do you recall how many +M procedures you had
17 actually performed prior to giving lectures for the
18 Prolift+M?

19 A I do not recall.

20 Q Do you recall if you did anything to confirm
21 that the +M, the Prolift+M was safe and effective prior
22 to giving lectures to other doctors about the product?

23 MR. DIPOLA: Object to form.

24 THE WITNESS: I'm sorry, repeat that.

1 BY MR. FAES:

2 Q Sure. Did you do anything to confirm that
3 the Prolift+M was safe and effective prior to giving
4 lectures to other doctors about the product?

5 A Yes.

6 Q What did you do?

7 A I've used hundreds of products that were the
8 similar application, just had a different mesh
9 material. The +M was just a lighter mesh material.
10 Variation of a theme.

11 Q Do you know whether the weight and pore size
12 of a mesh used in a product can have clinical effects
13 to the patient?

14 MR. DIPOLA: Object to form.
15 Applicable to Prolift, or applicable to all mesh?

16 BY MR. FAES:

17 Q Do you understand the question, Doctor?

18 A I do.

19 Q Let him answer then.

20 MR. DIPOLA: Object to form.

21 THE WITNESS: There is some
22 consideration that using less mesh at the time was
23 better than using more mesh, and that was the attempt
24 with the +M.

1 BY MR. FAES:

2 Q My question is actually a little bit
3 different than that, so I'm going to go ahead and reask
4 it.

5 Doctor, do you know whether or not there is a
6 difference in clinical impact to patients between a
7 lighter weight larger pore mesh and a heavier weight
8 smaller pore mesh, such as the mesh that was used in
9 the Prolift, versus the mesh that was used in the
10 Prolift+M?

11 MR. DIPOLA: Object to form. Beyond
12 the scope.

13 THE WITNESS: I'm not aware of any
14 clinical difference between those two materials.

15 BY MR. FAES:

16 Q Did you do anything to confirm that there was
17 indeed no clinical difference between the Prolift+M and
18 the other devices that you've implanted prior to giving
19 lectures to other doctors about the Prolift+M product?

20 MR. DIPOLA: Objection. Beyond scope.

21 THE WITNESS: Did I do anything
22 clinically to determine that, is that what you're
23 asking?

24

1 BY MR. FAES:

2 Q Let me see if I can reask it a different way,
3 because I'm not sure I was clear.

4 Doctor, prior to giving lectures about the
5 Prolift+M product, did you do anything to confirm that
6 the lighter weight larger pore mesh in the Prolift+M
7 didn't have any effect on clinical impact to women
8 versus the other products that you had had experience
9 with?

10 MR. DIPOLA: I object to this whole
11 line of questioning as this is not a Prolift
12 deposition. This is way beyond scope of the TVT
13 general deposition.

14 THE WITNESS: So in theory there's a
15 difference. There wasn't any clinical proof of it.

16 BY MR. FAES:

17 Q My question was did you do anything to
18 confirm before you went out and gave lectures to
19 physicians about the Prolift+M product that there was
20 indeed no difference between the mesh that was used in
21 the Prolift+M and the mesh that was used in the
22 Prolift?

23 MR. DIPOLA: Same objection.

24 THE WITNESS: It's hard to recall

1 exactly what we spoke about at the time, or how many
2 lectures I actually gave on the Prolift+M, but really
3 my role in discussing these things was to talk about
4 the use of products in the pelvic area with
5 polypropylene mesh, not so much the M versus the
6 regular, from my take.

7 MR. FAES: So I'm going to have to
8 object and move to strike that as nonresponsive.

9 BY MR. FAES:

10 Q My question is actually a little bit
11 different, and if you could, I'm going to have the
12 court reporter read it back, and if you could please
13 try to answer the question either yes or no. It's a
14 yes or no question, either yes or no, or if you can't
15 answer the question yes or no one way or the another,
16 or you don't know, you can answer that as well, and
17 then if you need to add an explanation, please do so.

18 (Record read by the court reporter.)

19 MR. DIPOLA: Same objection. Way
20 beyond scope.

21 THE WITNESS: So in evaluating the
22 Prolift+M product versus the regular Prolift product I
23 read the information on the two materials, I worked
24 with them in a cadaveric lab, and I had used them

1 clinically in a clinical setting to become familiar
2 with them and to notice the differences of one versus
3 the other.

4 BY MR. FAES:

5 Q Do you recall how many Prolift+Ms you used in
6 a clinical setting prior to giving lectures about the
7 Prolift+M product to other doctors?

8 MR. DIPOLA: Same objection. This is
9 not a Prolift+M deposition.

10 THE WITNESS: I do not recall.

11 BY MR. FAES:

12 Q Doctor, have you ever given a lecture or done
13 a speaking event about a product that you haven't used?

14 A No.

15 Q On the products that you have used, did you
16 ever do anything to confirm that the products were safe
17 and effective prior to giving lectures to other doctors
18 about those products?

19 MR. DIPOLA: Objection.

20 THE WITNESS: Yes.

21 BY MR. FAES:

22 Q What kind of things did you do before to
23 ensure that those devices were safe and effective prior
24 to giving lectures to other doctors?

1 A In most cases, aside from laboratory use,
2 cadaveric use, they were also preceded by some type of
3 clinical study.

4 Q So is it your testimony that you reviewed
5 clinical studies prior to giving lectures to other
6 doctors about every product that you've ever given
7 lectures on?

8 MR. DIPOLA: Objection.
9 Mischaracterizes.

10 THE WITNESS: Either I reviewed studies
11 or was involved with studies prior to somebody who
12 would advocate using a procedure.

13 BY MR. FAES:

14 Q Doctor, do you know the difference between a
15 laser cut and mechanical cut TVT product?

16 A To some extent, yes.

17 Q Explain that for me. What do you mean by to
18 some extent?

19 A Well, I'm not an expert on making mesh
20 materials, but I think as it applies, if you cut a
21 piece of mesh with a laser, it's known as laser cut,
22 and if you cut a piece of mesh with some kind of a
23 different cutting device, more of a mechanic device,
24 it's a mechanical cut material.

1 Q Do you know how to tell the difference
2 looking at the box between a mechanically cut TVT
3 retropubic product and a laser cut TVT product?

4 A No. Unless I was told, I wouldn't know.

5 Q So I would take it, then, that you don't keep
6 track of how many mechanical cut TVTs you've placed
7 versus laser cut?

8 A No.

9 Q And I would also take it that you have no
10 preference between a TVT -- strike that.

11 I would take it that you have no preference
12 between a TVT mesh that was laser cut or one that was
13 mechanically cut, you just take whatever the hospital
14 had on the shelf; is that fair?

15 MR. DIPOLA: Objection to form.
16 Mischaracterizes.

17 THE WITNESS: I would use a TVT device,
18 yes. Whether that's mechanically cut or not, it's of
19 no consequence. I would use a device.

20 BY MR. FAES:

21 Q Do you know whether the TVT Secure device
22 that you've used in the past is laser cut or
23 mechanically cut?

24 A I believe it was laser cut.

1 Q Do you know whether the TVT Abbrevio product
2 that you've used in the past is laser cut or
3 mechanically cut?

4 A I'm not sure.

5 Q Do you know whether the TVT Exact product
6 that you've used in the past is laser cut or
7 mechanically cut?

8 A I'm not sure.

9 Q So I take it because you don't even know the
10 difference between looking at the box between a
11 mechanically cut TVT retropubic product and a laser cut
12 TVT product, you've never tracked the difference -- how
13 that difference impacts your complication rates in your
14 practice, correct?

15 A Correct.

16 Q Have you ever tracked or looked at complaint
17 analysis or trends for mechanically cut mesh versus
18 laser cut mesh products?

19 A No.

20 Q Can we agree that you have a conflict of
21 interest in this litigation because of your
22 longstanding consulting relationship with Ethicon?

23 MR. DIPOLA: Object to form.
24 Mischaracterizes.

1 THE WITNESS: No. We cannot agree on
2 that.

3 BY MR. FAES:

4 Q Can we agree that you have a conflict of
5 interest in this litigation because of your
6 longstanding consultant -- strike that.

7 Can we agree that you have a conflict of
8 interest in this litigation because of your
9 longstanding consulting relationships with multiple
10 mesh manufacturers, including AMS, Boston Scientific,
11 and Bard?

12 A No. Can't agree on that.

13 Q So you don't agree that you're potentially
14 biased in favor of Ethicon; is that fair?

15 A Yeah, I think I've used all products, and
16 that's what makes me an expert in this area without
17 really any bias.

18 Q Would you agree that being paid the sum of
19 money that you've been paid by Ethicon could influence
20 your opinion?

21 A No.

22 Q Would you consider yourself an advocate of
23 mesh products?

24 A Yes.

1 Q Would you agree that you're not completely
2 objective in this case because you are an advocate of
3 mesh products?

4 MR. DIPOLA: Objection to form.
5 Argumentative.

6 THE WITNESS: No, I wouldn't agree with
7 that statement.

8 BY MR. FAES:

9 Q Would you agree that you have a financial
10 stake in the outcome of the mesh cases?

11 MR. DIPOLA: Object to form.

12 THE WITNESS: No. I have no financial
13 stake in the outcome of mesh cases.

14 BY MR. FAES:

15 Q So you don't believe that your practice could
16 be affected and you could be affected financially if
17 mesh products were no longer available for the
18 treatment of stress urinary incontinence or pelvic
19 organ prolapse?

20 MR. DIPOLA: Object to form.

21 THE WITNESS: I think it would be a
22 detriment to the women who have these problems if they
23 weren't available, but as far as my financial impact,
24 no, I do not feel it would be a financial hardship for

1 me if that were to happen.

2 BY MR. FAES:

3 Q Do you know when laser cut mesh was first
4 sold in the Ethicon TVT product?

5 A I have no idea.

6 Q When did you first learn about the fact that
7 there were two different types of TVT meshes, one that
8 was laser cut, and one that was mechanically cut?

9 A I think I became aware of it some time around
10 the introduction of TVT-S.

11 Q So you believe you first became aware of it
12 somewhere around 2006?

13 A Probably.

14 Q And did Ethicon make you aware of it because
15 you were a preceptor and lecturer for them on the TVT
16 Secure?

17 MR. DIPOLA: Object to form.

18 THE WITNESS: I really think it came
19 about just to find out how they made the products. I
20 don't think there was necessarily any thought process
21 that it would be better or worse than what they had
22 previously.

23 BY MR. FAES:

24 Q So you were never told by Ethicon that there

1 were potential benefits to laser cut mesh over
2 mechanically cut mesh in the fact that it may not fray
3 or fall apart?

4 MR. DIPOLA: Object to form.

5 THE WITNESS: I don't remember any clear
6 advantages being described, no.

7 BY MR. FAES:

8 Q Do you know who invented the TVT product?

9 A The retropubic?

10 Q Yes.

11 A I'm aware of Ulf Ulmsten and Peter Petros
12 working together on it.

13 Q Are you aware of how much money Dr. Ulmsten
14 was paid by Ethicon for the TVT product?

15 A No idea.

16 Q Are you aware of whether or not Dr. Ulmsten
17 was paid for the results of his clinical studies that
18 he published regarding the TVT product?

19 A No idea.

20 Q Doctor, do you think that inventors should be
21 allowed to participate in studies attempting to
22 establish the safety of a device on a product that they
23 invented?

24 A Yes.

1 Q Do you agree that allowing inventors to
2 participate in studies attempting to establish the
3 safety of a device on a product that they invented
4 introduces potential bias?

5 MR. DIPOLA: Object to form.

6 THE WITNESS: Anything can potentially
7 introduce a bias, but I would like to think that that
8 would not be the cause of the bias.

9 BY MR. FAES:

10 Q Doctor, I take it that you -- have you ever
11 met Dr. Ulf Ulmsten?

12 A He passed away a while ago. I think I met
13 him once indirectly.

14 Q Do you recall where that was?

15 A I do not.

16 Q Do you recall whether or not it was in the
17 United States or if it was in Sweden?

18 A It was not in Sweden.

19 Q Have you ever met Dr. Cosson?

20 A Not that I recall.

21 Q Do you know who Dr. Cosson is?

22 A No.

23 Q So I take it that you did not go to France to
24 train with Dr. Cosson on the Prolift product?

1 A Correct.

2 Q Are you aware that there hasn't been a single
3 transvaginal product launched by Ethicon since the
4 TVT-O was launched in January of 2004 that has used
5 mechanically cut mesh?

6 MR. DIPOLA: Object to form.

7 THE WITNESS: Not aware of that.

8 (Pause.)

9 BY MR. FAES:

10 Q Doctor, would you agree with me that when you
11 give your opinions in this case you want your opinions
12 to be as accurate as possible?

13 A Yes.

14 Q Would you agree that you would want to be as
15 thorough in your review of the available information,
16 documents, and literature as possible?

17 A Yes.

18 Q And you wanted to make sure that you got all
19 of the information on the pertinent issues in the case
20 before giving your opinions, correct?

21 A Correct.

22 Q Would you agree that you want to get both
23 sides of the story before issuing your opinions as an
24 expert in any case?

1 A Yes.

2 Q Would you agree that that's important to you
3 as an expert in giving your opinions?

4 A Yes.

5 Q Doctor, I'm going to have you look again at
6 your reliance list. I think it's marked as Exhibit 3.
7 Tell me if I'm wrong.

8 A Reliance list, 7.

9 Q Seven, my apologies. So looking at your
10 reliance list marked as Exhibit number 7. Is it your
11 testimony that you only spent one to two hours
12 reviewing all the materials in this lengthy document?

13 MR. DIPOLA: Object to form.

14 THE WITNESS: Well, as I stated before,
15 a lot of these had been read before, and some of these
16 were added to after discussion by some of the
17 assistants in the law firm, so I didn't necessarily
18 read over each and every one of these articles in one
19 or two hours, if that's what you're thinking, but these
20 are articles that came to mind when considering these
21 types of cases.

22 BY MR. FAES:

23 Q Well, if you look at the portion after the
24 literature section, you can see that there are four

1 pages of internal documents, plus an additional page of
2 publicly available materials. Do you see that?

3 A I do.

4 Q So I just want to be clear for the record,
5 it's your testimony that in addition to the literature
6 materials, some of which you may have reviewed before,
7 you were able to review all the materials on those
8 additional five pages within one to two hours?

9 A Those were materials that were discussed, and
10 as I said, I didn't miss -- I read over each and every
11 one of them, but we discussed some, and I was aware
12 that they were including them in the reference list.

13 Q Have you reviewed any deposition testimony of
14 any Ethicon corporate employees such as medical
15 directors or scientists or any of those people who have
16 developed the TVT product?

17 A I have not read any specific depositions.

18 Q Well, if you look at the last page of your
19 expert report -- strike that.

20 If you look at the last page of your reliance
21 material you have three expert reports cited. Do you
22 see that?

23 A I do.

24 Q It's Dr. Blaivas's, Dr. Elliot's and

1 Dr. Rosenzweig's reports, right?

2 A Yes.

3 Q And you also state that you've reviewed and
4 relied upon the materials cited in their reports?

5 MR. DIPOLA: As per the updated amended
6 reliance list those reports have been deleted.

7 THE WITNESS: I have to clarify that. I
8 didn't understand your initial question. You made it
9 sound as if there were depositions from employees at
10 Gynecare. These depositions I did actually read
11 through with Dr. Blaivas specifically.

12 BY MR. FAES:

13 Q Oh, so you're saying that you read
14 Dr. Blaivas's deposition?

15 A I definitely read Dr. Blaivas's, and I think
16 some of the other individuals as well. I thought you
17 meant they're employees of Gynecare.

18 Q That was actually not my question, but I
19 appreciate you offering that. So I'll be clear on what
20 my question is.

21 Are you aware that Dr. Blaivas, Elliot, and
22 Dr. Rosenzweig have cited dozens of depositions of
23 Ethicon corporate employees within their reports?

24 A If they were in there, then I must have seen

1 them.

2 Q So it's your testimony that you reviewed
3 dozens of Ethicon employee transcripts in the one to
4 two hours that you spent --

5 MR. DIPOLA: Objection. This totally
6 mischaracterizes.

7 THE WITNESS: I stated that I read --
8 BY MR. FAES:

9 Q I'll restate it. Doctor, is it your
10 testimony that you've reviewed the dozens of Ethicon
11 corporate deposition employees cited in
12 Dr. Rosenzweig's, Elliot's, and Blaivas's reports in
13 one to two hours?

14 A No.

15 Q Have you reviewed those reports?

16 A I've stated that I reviewed Dr. Blaivas's
17 report. I did not state I reviewed dozens of other
18 employee depositions.

19 Q Well, it also states that you reviewed the
20 materials cited in Dr. Blaivas's report, is that true
21 or not true?

22 A I reviewed his report, but not necessarily
23 each and every reference that he listed.

24 Q Is there a listing of the references he cited

1 that you did review somewhere that could be made
2 available?

3 A Not that I know of.

4 Q So you would agree with me that you haven't
5 reviewed all the materials cited in Dr. Blaivas's
6 expert report, correct?

7 MR. DIPOLA: Object to form.

8 THE WITNESS: No, I have not looked at
9 each and every reference that he cited individually,
10 no.

11 BY MR. FAES:

12 Q And you would agree with me that you haven't
13 reviewed all the materials cited in Dr. Elliot's expert
14 report?

15 A In a similar way, yes, you're correct.

16 Q And you would agree with me that you haven't
17 reviewed all the materials cited in Dr. Rosenzweig's
18 expert report?

19 A Correct.

20 Q Would you agree with me if there are
21 documents that you haven't reviewed, you can't be
22 relying on them?

23 A There could have been documents in those
24 discussed, so I'm familiar with them, but I haven't

1 read the individual document.

2 Q My question is actually a little different
3 than that. Would you agree with me that if you haven't
4 reviewed, actually reviewed a document, you can't be
5 relying on it for the opinions that you intend to
6 express in this case?

7 MR. DIPOLA: Object to form.
8 Mischaracterizes.

9 THE WITNESS: I think the difference
10 we're having is in the description of reviewed. If you
11 mean read every word, then that's different than had a
12 discussion or looked at someone's referencing of that
13 particular article.

14 BY MR. FAES:

15 Q So you don't think it's important to read
16 every word of a document before relying on it for the
17 opinions that you intend to offer in this case?

18 MR. DIPOLA: Object to form.

19 THE WITNESS: I think to read every word
20 of every referenced document might be challenging. I
21 think you can give an opinion without necessarily
22 having read every word. I'm giving my opinion. Not
23 necessarily their opinion.

24

1 BY MR. FAES:

2 Q Would you agree that if you don't read every
3 word on a document that you're relying on for your
4 opinions in the case, it's possible that you may miss
5 vital information that may change the opinions in this
6 case?

7 MR. DIPOLA: Object to form.

8 THE WITNESS: Again, I can only speak to
9 in accordance with my opinion versus someone else's.

10 BY MR. FAES:

11 Q And what is your opinion on that question?

12 A My opinion is that I'm an expert in this
13 area, and I can give an opinion on this topic of
14 discussion even if I haven't read every word of someone
15 else's opinion.

16 Q Would you agree that there could be
17 information out there either in published literature or
18 in the form of internal documents that you haven't seen
19 that could change your opinion in this case?

20 A I suppose anything is possible, but I think
21 my expert opinion is pretty unwavering based on my
22 expertise.

23 Q Are you aware that there was an update to the
24 TVT IFU in 2015 of this year?

1 A I'm not specifically aware of that update.

2 Q Doctor, do you intend to offer an opinion in
3 this case that warnings in the TVT IFU were sufficient
4 to warn physicians about the risks of the device?

5 MR. DIPOLA: Object to form.

6 THE WITNESS: I think as a physician
7 what's written in the IFU is not necessarily as
8 important as what one's peers do and what's published
9 in the literature.

10 BY MR. FAES:

11 Q That was not my question. My question is, do
12 you intend to offer an opinion in this case that the
13 adverse events and risks listed in the TVT IFU were
14 sufficient to warn physicians of the risks of the
15 device?

16 MR. DIPOLA: Same objection.

17 THE WITNESS: I could offer an opinion
18 on that.

19 BY MR. FAES:

20 Q So you do intend to offer an opinion in that
21 regard?

22 A I would offer an opinion in that regard.

23 Q Don't you think it would be important prior
24 to offering an opinion on that topic to know that there

1 was a significant update to the TVT IFU in April of
2 this year?

3 A Well, yes, but my opinion still stands that
4 the IFU isn't really what's relied upon by physicians
5 to look for adverse events. Most physicians probably
6 don't even read the IFUs.

7 Q Let me ask you this, Doctor, in practice do
8 you read the IFU for each mesh kit before using it?

9 MR. DIPOLA: Object to form.

10 THE WITNESS: No.

11 BY MR. FAES:

12 Q Do you assume that the IFU is disclosing to
13 you each of the risks and complications the company
14 knew could occur with the device or kit that you're
15 using?

16 A I rely more upon surgeons and my colleagues
17 in the community and the medical societies than I do on
18 a paper written by a company.

19 Q That's actually not my question. I'm not
20 asking what you rely more or less on. What I'm asking
21 you is, do you assume that when you read an IFU from a
22 company regarding a mesh kit, that the company is
23 disclosing to you those complications and risks that
24 could be significant for the patient that were known to

1 the company?

2 MR. DIPOLA: Objection to form.

3 THE WITNESS: Yes.

4 BY MR. FAES:

5 Q Do you assume that when you read an IFU for a
6 medical device that the company is disclosing any risks
7 and complications that would be inherent to the mesh
8 material so you would know what those risks are?

9 MR. DIPOLA: Object to form.

10 THE WITNESS: I mean, again, as a
11 surgeon, the IFU really is of secondary importance to
12 what's happening in the medical community, so I would
13 use that as a starting point, perhaps, but I would rely
14 more on other individuals.

15 BY MR. FAES:

16 Q Would you agree that the company that
17 manufactures the particular mesh material is in the
18 best position to know any specific risks or
19 complications that are inherent to that specific mesh
20 material?

21 A I think it's a complicated question, because
22 what mesh looks like on a bench or in an animal could
23 be different than what happens clinically. So I think
24 we've learned to rely more on what we see in the

1 clinical setting than on the bench setting.

2 MR. FAES: I'm going to object and move
3 to strike, and I'm going to have the court reporter
4 read back the question, because my question was fairly
5 specific, and I think it's a yes or no answer. If you
6 can answer it yes or no, or if you can't answer it yes
7 or no, please let me know one way or the other.

8 MR. DIPOLA: He's free to answer it any
9 way he wants. Please read it back.

10 (Record read by the court reporter.)

11 THE WITNESS: No.

12 BY MR. FAES:

13 Q Who do you think is in the best position to
14 know the specific risks of a specific mesh material,
15 keeping in mind that the polypropylene in the TVT is
16 different from the polypropylene in the AMS product
17 than the polypropylene in the Boston Scientific
18 product.

19 MR. DIPOLA: Object to the form of the
20 question.

21 THE WITNESS: I think that material
22 that's produced, if it's a type one mesh, which all the
23 ones that you mentioned were, that they're all fairly
24 similar. How they're going to react in an inpatient or

1 in a clinical setting is different than what might be
2 predicted in a laboratory or in an animal setting, so I
3 think it's hard to know how that material is going to
4 be until you have some clinical application.

5 BY MR. FAES:

6 Q Doctor, as you sit here today, do you have
7 any understanding of any standard whatsoever as to what
8 risks and complications are supposed to be disclosed in
9 an IFU?

10 A No.

11 Q So you're not relying on any objective
12 standard from any source?

13 A Correct.

14 Q Have you made any effort before today to find
15 out what FDA regulations require a medical device
16 company to disclose in an IFU?

17 MR. DIPOLA: Object to form.

18 THE WITNESS: No.

19 BY MR. FAES:

20 Q Would you agree that your background and
21 experience is not necessarily the same as all other
22 doctors who use medical devices?

23 A Yes.

24 Q Would you agree that your background and

1 experience is not necessarily the same as all other
2 doctors who might use the TVT?

3 A Yes.

4 MR. DIPOLA: Object to form.

5 THE WITNESS: Yes.

6 BY MR. FAES:

7 Q Doctor, unfortunately your expert report
8 doesn't have numbers, but under your conclusion section
9 you state that you have an intimate understanding of
10 what the reasonably prudent pelvic floor surgeon should
11 know about the risks and benefits of pelvic floor
12 procedures, the adequacy of the warnings in the IFUs,
13 the management of mesh complications, and the well
14 known risks that are associated with any pelvic floor
15 surgery. Do you see that?

16 A I do.

17 Q Is that an opinion you intend to offer in
18 this case?

19 A Yes.

20 Q Now, I notice your language here is talking
21 about a pelvic floor surgeon and pelvic floor surgery.
22 Do you consider the TVT device to be a pelvic floor
23 surgery?

24 A Yes.

1 Q What are you relying on for your
2 understanding of what a reasonably prudent pelvic floor
3 surgeon should know about the risks and benefits of
4 pelvic floor procedures and the adequacy of warnings in
5 IFUs?

6 MR. DIPOLA: Object to form.

7 THE WITNESS: I think the pelvic floor
8 surgeon should be someone who is either trained in
9 urology or gynecology and has experience with operating
10 in the vaginal area. I think they've had to go through
11 a residency program, perhaps a fellowship training
12 program so that they are familiar with how to operate
13 and do dissections in this area, and then I think they
14 need to understand the complications and pitfalls that
15 could be present in the pelvic floor, or in the vaginal
16 area, such as bleeding, nerve complications, bowel,
17 bladder, and muscular complications.

18 BY MR. FAES:

19 Q My question is actually a little different.
20 What I'm asking is, what are you relying on for what a
21 reasonably prudent pelvic surgeon should or shouldn't
22 know about the risks and benefits of pelvic floor
23 procedures?

24 MR. DIPOLA: Object to form.

1 BY MR. FAES:

2 Q Have you done any kind of study in that
3 regard, any kind of formal study?

4 A No.

5 Q Have you done any kind of survey of pelvic
6 floor surgeons to say what are the risks you know about
7 of this procedure or that procedure or anything like
8 that?

9 A No surveys, no.

10 Q So would it be fair to say that you're
11 primarily relying on your personal experience as a
12 pelvic floor surgeon for those opinions?

13 MR. DIPOLA: Object to form.

14 THE WITNESS: It is my expert opinion,
15 yes, you are correct. It's my opinion.

16 BY MR. FAES:

17 Q Doctor, have you ever known about a
18 complication from your own experience that another
19 doctor might not know about?

20 MR. DIPOLA: Object to form.

21 THE WITNESS: Wow, that's a tough
22 question to answer.

23 BY MR. FAES:

24 Q Let me see if I can narrow it for you. I'll

1 withdraw it and ask another question, because I think
2 it's vague.

3 MR. DIPOLA: A little strange.

4 BY MR. FAES:

5 Q Would you agree that you might know about a
6 complication from the TVT device or procedure from your
7 own experience that another doctor might not know
8 about?

9 A Again, it's somewhat broad. It depends on
10 what type of doctor. Pediatrician certainly wouldn't.
11 Another person who operates in this area and has gone
12 to lectures on it, I think we try to expose them to all
13 the complications that exist if they're going to choose
14 to do the procedure.

15 Q Let me reask it and I'll see if I can narrow
16 it a little bit more.

17 Doctor, would you agree that you might know
18 about a complication with the TVT device or procedure
19 from your own experience that another pelvic floor
20 surgeon might not know about?

21 MR. DIPOLA: Object to form.

22 THE WITNESS: I guess I would have to
23 say yes.

24

1 BY MR. FAES:

2 Q Have you ever studied the question of what
3 information needs to be in a pelvic mesh IFU. Have you
4 ever engaged in the study of that question?

5 A No.

6 Q Have you ever made any effort to confirm that
7 your understanding for what needs to be in an IFU is
8 consistent with what other doctors believe should be in
9 an IFU?

10 MR. DIPOLA: Object to form.

11 THE WITNESS: No.

12 BY MR. FAES:

13 Q In doing your work on this case, were you
14 ever curious as to what the regulatory affairs
15 professionals department at Ethicon, who are the
16 professionals who are required to make sure that the
17 TVT IFU complies with FDA regulations, are you curious
18 about what they thought needed to be included in the
19 IFU?

20 MR. DIPOLA: Object to form. Vague,
21 overbroad.

22 THE WITNESS: Curious, yes.

23 BY MR. FAES:

24 Q Doctor, would you agree that one of the risks

1 of the TVT procedure is acute and/or chronic pain?

2 A Yes.

3 Q Would you agree that one of the risks of the
4 TVT procedure is voiding dysfunction?

5 A Yes.

6 Q Would you agree that one of the risks of the
7 TVT procedure is pain with intercourse which in some
8 patients may not resolve?

9 A Yes.

10 Q Would you agree that one of the risks of the
11 TVT procedure is neuromuscular problems including acute
12 and/or chronic pain in the groin, thigh, leg, pelvic,
13 and/or abdominal area?

14 MR. DIPOLA: Object to form.

15 Overbroad.

16 THE WITNESS: Yes.

17 BY MR. FAES:

18 Q Do you agree that one of the risks of the TVT
19 procedure is recurrence of incontinence?

20 A Yes.

21 Q Would you agree that one of the risks of the
22 TVT procedure is bleeding including hemorrhage or
23 hematoma?

24 A Yes.

1 Q Would you agree that one of the risks of the
2 TVT procedure is that one or more surgeries may be
3 necessary to treat those adverse reactions?

4 A Yes.

5 Q Would you agree that one of the risks of the
6 TVT procedure is seroma?

7 A Yes.

8 Q Urge incontinence?

9 A Yes.

10 Q Urinary frequency?

11 A Yes.

12 Q Urinary retention?

13 A Yes.

14 Q Adhesion formation?

15 A Yes.

16 Q Atypical vaginal discharge?

17 A Yes.

18 Q Exposed mesh that may cause pain or
19 discomfort to the patient's partner during intercourse?

20 A Yes.

21 Q Death?

22 A Yes.

23 Q Do you believe it would be reasonable to
24 include those risks in the adverse events section of

1 the TVT IFU?

2 MR. DIPOLA: Object to form.

3 THE WITNESS: Yes, it would be

4 reasonable.

5 BY MR. FAES:

6 Q Do you believe that those risks that I just

7 read to you should be included in the TVT IFU?

8 A Yes.

9 Q Do you know whether or not those risks were

10 in the IFU prior to May of 2005?

11 A Not sure.

12 Q But you don't believe it would be unnecessary

13 to have any of those adverse reactions in the TVT IFU?

14 A I think it's reasonable to have those in

15 there. I just stated before I don't think physicians

16 rely on the IFU.

17 Q Doctor, if Ethicon medical affairs believe

18 that a caution needed to be taken by a doctor before

19 using a TVT in a particular woman, do you believe that

20 caution should be put in the IFU?

21 MR. DIPOLA: Object to form. Vague.

22 THE WITNESS: I think it's reasonable to

23 put it in there.

24 MR. FAES: Do you mind if we take a

1 quick break. I think I've got a half hour left. I'll
2 get organized and we'll cruise on through.

3 (Recess: 7:15 p.m. to 7:21 p.m.)

4 BY MR. FAES:

5 Q Doctor, we're back on the record after a
6 short break. Are you ready to proceed?

7 A Yes.

8 Q Doctor, would you agree that if Ethicon or
9 Johnson & Johnson said something in the TVT IFU that
10 they knew not to be true, would you agree that that
11 would be wrongful?

12 MR. DIPOLA: Object to form.

13 THE WITNESS: Yes.

14 BY MR. FAES:

15 Q If Ethicon or Johnson & Johnson made claims
16 about the mesh in the TVT that they had no data to
17 support, would you agree that that would be wrongful?

18 MR. DIPOLA: Object to form.

19 Hypothetical.

20 THE WITNESS: Yes.

21 BY MR. FAES:

22 Q Are you aware of anything in the TVT IFU as
23 to which anyone at Ethicon has admitted there was not
24 data to support the claim about the mesh?

1 A No.

2 Q Are you aware of anything in the TVT IFU as
3 to which someone at Ethicon has admitted there was a
4 claim in the IFU about the mesh that was misleading?

5 A No.

6 Q If that occurred, would you agree that that
7 would be a failure to provide adequate and appropriate
8 warnings about TVT?

9 MR. DIPAOLO: Objection to form.

10 THE WITNESS: Yes.

11 BY MR. FAES:

12 Q Are there any specific risks and
13 complications that you believe need to be in the TVT
14 IFU?

15 MR. DIPAOLO: Object to form.

16 THE WITNESS: Well, again, I don't think
17 it's something that's solely relied upon by the
18 surgeon, but I think anybody using the device should be
19 aware of certain complications. Do they need to find
20 that out from the IFU, probably not, but they should be
21 aware of what they're using and what the potential
22 complications are.

23 BY MR. FAES:

24 Q What complications do you believe those are?

1 Do you have a list?

2 A Well, I think a lot of them were things that
3 you had mentioned previously. I think that was a
4 pretty comprehensive list that you mentioned.

5 Q Doctor, once an IFU is out there, if Ethicon
6 learned of a risk or complication that was not
7 previously warned about in the IFU, and it was a
8 significant risk or complication in terms of the harm
9 it could cause to a woman, do you know whether or not
10 Ethicon had any obligation to get that information out
11 to doctors?

12 A Well, when you say they had an obligation,
13 had a legal obligation, or just a moral obligation?
14 I'm not sure what you mean by am I aware that they had
15 an obligation to.

16 Q Well, let's address it both ways. First of
17 all, do you believe they have a moral obligation?

18 A Well, yes, I personally believe that if there
19 is something that could potentially benefit the
20 physician to know about a product that's being on the
21 market, then they should have that information.

22 Q Do you know whether -- do you have an opinion
23 of whether they're legally required to get that
24 information out?

1 MR. DIPOLA: Object to form.

2 THE WITNESS: That I do not know.

3 BY MR. FAES:

4 Q Would you agree that for a mesh to be
5 successfully used in pelvic floor surgery it should be
6 soft and compliant with a woman's vaginal tissues?

7 MR. DIPOLA: Object to form.

8 THE WITNESS: I'm not sure that that
9 specifically qualifies as a mesh that needs to be used
10 or should be used for pelvic floor surgery.

11 BY MR. FAES:

12 Q So you don't believe it's possible for a mesh
13 to be too stiff or not soft and compliant enough to be
14 successfully used in the pelvic floor?

15 MR. DIPOLA: Object to form.

16 THE WITNESS: I'm just not sure how you
17 define soft and compliant.

18 BY MR. FAES:

19 Q Let me ask it a different way. Would you
20 agree that there could be a mesh that could be too
21 stiff to be used successfully in a woman's vaginal
22 tissues?

23 MR. DIPOLA: Object to form.

24 Hypothetical.

1 THE WITNESS: Yes, there could be.

2 BY MR. FAES:

3 Q Would you agree that there could be a mesh
4 that could be too stiff to use in a midurethral
5 polypropylene sling for the treatment of stress urinary
6 incontinence?

7 A Sure. There could be.

8 Q I take it, Doctor, you're familiar with the
9 Gynemesh PS product which is the product that's used in
10 the Prolift and Prosima device?

11 MR. DIPOLA: Again, object to form.

12 This is not a Gynemesh or Prolift deposition.

13 THE WITNESS: Familiar in what way? I'm
14 just not sure what you mean by familiar.

15 BY MR. FAES:

16 Q Well, you're familiar that it's a different
17 mesh than what's used in the TVT, correct?

18 A I'm not familiar with the differences in the
19 mesh.

20 Q I'll take it then that you're not familiar
21 with the fact that the Gynemesh PS mesh is less stiff
22 than the mesh that's used in the TVT?

23 MR. DIPOLA: Object to form. Way out
24 of the scope.

1 THE WITNESS: I'm not really familiar
2 with the differences in the different meshes.

3 BY MR. FAES:

4 Q Would you ever consider using the Gynemesh PS
5 material as a -- strike that.

6 Would you ever consider using the Gynemesh PS
7 material as a mesh material in a sling for the
8 treatment of stress urinary incontinence?

9 MR. DIPAOLO: Object to form.
10 Hypothetical, out of the scope.

11 THE WITNESS: No.

12 BY MR. FAES:

13 Q Why is that?

14 A Because it's not meant to be used for that.

15 Q Do you know whether or not there are doctors
16 that have in fact used it for the treatment of stress
17 urinary incontinence?

18 MR. DIPAOLO: Object to the form.
19 Hypothetical. Assumes.

20 THE WITNESS: Not aware.

21 BY MR. FAES:

22 Q Would you ever consider using the Ultrapro
23 mesh, which is the mesh that's used in the Prolift+M
24 for the treatment of stress urinary incontinence in a

1 sling?

2 MR. DIPOLA: Same objection to any
3 question that refers to Prolift or pelvic organ
4 prolapse devices. This is not that deposition.

5 MR. FAES: I'm not asking about pelvic
6 organ prolapse devices. I'm asking about mesh. But go
7 ahead.

8 THE WITNESS: I would not use those
9 meshes, no.

10 BY MR. FAES:

11 Q Why is that?

12 A They're not intended for that use.

13 Q Do you know whether or not other surgeons
14 have in fact used that material in slings for the
15 treatment of stress urinary incontinence?

16 MR. DIPOLA: Objection to form.

17 THE WITNESS: I'm not aware of it, no.

18 BY MR. FAES:

19 Q Do you know whether or not there are in fact
20 clinical studies that have been published utilizing
21 that mesh for the treatment of stress urinary
22 incontinence in women?

23 A I couldn't quote the exact study, no. I'm
24 not aware of a study.

1 Q Would you agree that clinically there may be
2 an impact of increased rigidity with any given mesh as
3 it may increase vaginal stiffness postoperatively with
4 the potential to impair sexual dysfunction?

5 MR. DIPOLA: Object to form. Vague.

6 THE WITNESS: I'm sure it's possible.

7 BY MR. FAES:

8 Q Would you agree that any future meshes
9 developed by Ethicon for use in the pelvic floor should
10 be less rigid than the mesh that's used in the TVT?

11 MR. DIPOLA: Totally hypothetical.
12 Object to form.

13 THE WITNESS: I wouldn't necessarily
14 agree with that.

15 BY MR. FAES:

16 Q So if Ethicon medical's directors believe
17 that that was an appropriate goal in 2009, you would
18 disagree with that?

19 A What was the goal in 2009?

20 Q If Ethicon's medical directors believed that
21 that was an appropriate goal in 2009, you would
22 disagree with that?

23 A What was the goal? The goal of developing --

24 Q I'll restate the entire question.

1 A Yes.

2 Q If Ethicon's medical directors believed in
3 2009 that was an appropriate goal for all future meshes
4 used in pelvic surgery to be less rigid than the mesh
5 in the TVT, you would disagree with that?

6 MR. DIPOLA: Again, object to form.

7 THE WITNESS: I don't know if I disagree
8 with that statement. You would have to put it into
9 context. I think there are certain circumstances where
10 I would agree with it.

11 BY MR. FAES:

12 Q Would you agree or disagree that clinical
13 trials show that large pore meshes provide better
14 patient comfort than standard meshes?

15 MR. DIPOLA: Object to form. Vague.

16 THE WITNESS: I would not necessarily
17 agree with that, no.

18 BY MR. FAES:

19 Q So I would take it that you would also
20 disagree that the clinical trials show that large pore
21 meshes provide better patient comfort than standard
22 meshes because there's lower scar tissue formation and
23 lower stiffness, correct?

24 A I guess it all depends on where you're

1 putting the mesh in, and what you're trying to achieve
2 with it. For a larger piece of material, perhaps for
3 prolapse, maybe you would want to use a larger pore
4 material.

5 Q So you believe the location in the body that
6 the mesh is placed has an impact on whether or not
7 large pore meshes provide better patient comfort than
8 standard meshes?

9 A I think it's location and amount of material
10 with length. I think it all plays a role.

11 Q So I'm just trying to understand your
12 opinions, Doctor. Do you agree or disagree in general
13 that clinical trials show that large pore meshes
14 provide better patient comfort than standard meshes,
15 and that the reason for that is due to lower scar
16 tissue formation and lower stiffness?

17 A I think I would agree with that, but the
18 caveat to that would be depending on where it's used as
19 to the applicability of that statement. I think if you
20 have a smaller piece of material in a different
21 location, that maybe that would not play as much of a
22 role, and it may in some ways affect the strength in
23 what you're trying to achieve with a certain piece of
24 material.

1 Q Doctor, would you agree that the Burch
2 procedure is within the standard of care for the
3 treatment of stress urinary incontinence?

4 A Yes.

5 Q Would you agree that the native tissue sling
6 is within the standard of care for the treatment of
7 stress urinary incontinence?

8 A Yes.

9 Q Would you agree that the pubovaginal sling is
10 within the standard of care for the treatment of stress
11 urinary incontinence?

12 A Yes.

13 Q Do you know whether or not the TVT mesh is
14 manufactured from the same material as the Prolene
15 suture?

16 A I have no idea.

17 Q You don't know one way or the other?

18 A I know it's polypropylene, it's the same
19 material. I don't know the details. I don't
20 manufacturer mesh. I don't know. I don't know the
21 subtleties in how to manufacture mesh.

22 Q Would you agree that a polypropylene suture
23 has a different safety and efficacy profile than a TVT
24 device?

1 MR. DIPOLA: Object to form.

2 THE WITNESS: I'm not sure how to answer
3 that. I mean, it's -- in terms of the material, it may
4 be similar material. It's all about how you use the
5 material you have, more so than the material that
6 exists.

7 BY MR. FAES:

8 Q Let me ask you this, do you know how many
9 more times -- strike that.

10 Do you know how many more times material
11 there is in a TVT mesh than there is in a polypropylene
12 suture?

13 A No.

14 Q But you would agree that there is
15 significantly more polypropylene material in a TVT
16 sling than there is in a polypropylene suture, correct?

17 A Theoretically, yes.

18 Q I'm going to have to reask that, because I
19 said polypropylene suture, and I meant Prolene suture.

20 You would agree that there are many times
21 more material in a TVT mesh than there is in a Prolene
22 suture, correct?

23 A Yes.

24 Q Would you agree that the amount -- strike

1 that.

2 Would you agree that this additional amount
3 of material in the TVT mesh could lead to more foreign
4 body reactions?

5 MR. DIPOLA: Object to form.

6 THE WITNESS: Sure, yes.

7 BY MR. FAES:

8 Q Would you agree that the additional amount of
9 material in the TVT mesh could lead to a greater
10 infection risk?

11 MR. DIPOLA: Object to form.

12 THE WITNESS: It's hard to say with
13 certainty whether that's true or not.

14 BY MR. FAES:

15 Q Is there a risk of infection from mesh with
16 the TVT?

17 A Yes.

18 Q Doctor, what is the proper way to tension the
19 TVT device?

20 A That's a tough question. There is no
21 quote/unquote proper way to tension the TVT device,
22 there are many different ways to do it, and I think it
23 relies on the surgeon's experience as to what works for
24 them on how best to tension it.

1 (Plaintiff's Exhibit 22, Article by
2 Dr. Serels Bates 09125791 and 792: Marked for
3 Identification.)

4 BY MR. FAES:

5 Q Doctor, I'm going to hand you what's been
6 marked as Exhibit 22 to your deposition, and this
7 appears to be an article or a piece written by you
8 titled, Are All Slings Created Equal. Do you see that?

9 A I do.

10 Q Do you recall writing this piece?

11 A I do.

12 Q Do you recall when you wrote this particular
13 piece?

14 A Not exactly, but several years ago.

15 Q What I specifically want to ask you a
16 question about, Doctor, is paragraph four where it
17 states, One of the biggest concerns in all
18 procedures -- strike that.

19 It says, One of the biggest concerns in all
20 sling procedures is how to tension the sling. Most
21 people use a spacing device and insert it between the
22 urethra and the sling as they pull up to set the
23 tension, or a cough test for use with the retropubic
24 and obturator slings. Do you see that?

1 A Yes.

2 Q Do you agree that one of the biggest concerns
3 in all sling procedures is how to tension the sling?

4 A Yes.

5 Q Do you believe that the company that
6 manufacturers the device is responsible to tell
7 physicians how to properly tension and place the
8 device?

9 MR. DIPOLA: Object to form.

10 THE WITNESS: Those are two different
11 things. To properly place the device or properly
12 tension the device.

13 BY MR. FAES:

14 Q Fair point. I'll withdraw that question and
15 ask another one.

16 Do you believe that Ethicon is responsible to
17 tell physicians how to properly tension the device?

18 A No.

19 Q So even though as we saw earlier with your
20 Prosima questionnaire that you filled out that you
21 think it's important to have a standardized procedure,
22 you don't think it's the company's responsibility to
23 properly and adequately describe how to tension the TVT
24 device in the instructions for use?

1 A No.

2 Q Do you have an opinion in this case as to
3 whether or not Ethicon does or does not properly
4 instruct physicians on how to tension the TVT device?

5 A I'm sorry, repeat the question one more time.

6 Q Do you have an opinion in this case regarding
7 whether or not Ethicon does or does not properly
8 instruct physicians on how to tension the TVT device?

9 MR. DIPOLA: Objection to form.

10 THE WITNESS: My opinion is that I don't
11 think it's the device company's responsibility to teach
12 someone how to tension the sling. I mean, slings have
13 been around long before the TVT product came out.

14 BY MR. FAES:

15 Q Would you agree that Ethicon does describe
16 how to tension the TVT device in its instructions for
17 use?

18 A I think it's -- there are vague suggestions
19 on how to tension a sling of any sort, but it's really
20 up to the discretion of the surgeon on how they want to
21 perform the procedure.

22 Q Do you know whether or not there are
23 differences between the different TVT products, the
24 TVT, TVT-O, or the TVT Abbrevio with regard to how the

1 instructions for use instructs the physicians how to
2 tension that device?

3 A I'm not familiar with the differences in the
4 IFUs.

5 Q Do you know whether or not the TVT IFU
6 directs physicians to place the TVT without tension?

7 MR. DIPOLA: Object to form.

8 THE WITNESS: I'm not sure, but
9 certainly it's been described as a tension free device,
10 but that's always been somewhat of a misnomer amongst
11 surgeons.

12 BY MR. FAES:

13 Q Do you know whether or not the TVT IFU
14 directs the physician to place the TVT device with
15 minimal tension?

16 MR. DIPOLA: Object to form.

17 THE WITNESS: I don't know specifically
18 if it says that.

19 BY MR. FAES:

20 Q Do you know whether the TVT device actually
21 says both things. In one spot it tells the physician
22 to place it with tension, and in another spot it tells
23 them to place it with minimal tension?

24 A I'm not familiar with those IFUs to the

1 extent that I remember seeing either of those terms.

2 Q Would you agree that describing tensioning of
3 the device of the TVT with tension is different from
4 describing it with minimal tension?

5 MR. DIPOLA: Object to form.

6 THE WITNESS: I think with or without
7 tension to different surgeons means different things,
8 and I think as a surgeon, you need to realize how best
9 to use a product in your own hands based on your
10 experience and the experience of your peers, and I
11 really don't think many people rely upon an IFU to make
12 that determination. I certainly don't.

13 BY MR. FAES:

14 Q Do you know whether or not physicians were
15 asking Ethicon medical affairs for instructions on how
16 to properly tension the TVT IFU?

17 A I do not know if they were asking that
18 question.

19 Q Would you agree that the strongest unmet need
20 with the TVT is the ability to adjust tension both
21 intraoperatively and postoperatively?

22 MR. DIPOLA: Object to form.

23 THE WITNESS: I would not agree with
24 that.

1 (Plaintiff's Exhibit 23, Article by
2 Dr. Serels Bates 02602980 through 984: Marked for
3 Identification.)

4 BY MR. FAES:

5 Q I'm going to hand you, Doctor, what's been
6 marked as Exhibit 23 to your deposition.

7 A Sure.

8 Q And this is an article by you titled,
9 Thoughts on Midurethral Synthetic Slings. Do you see
10 that?

11 A I do.

12 Q And this was written in 2007?

13 A Okay.

14 Q I really only want to ask you about one
15 thing. Starting at the bottom of the second page and
16 continuing on to the third, it states, Perhaps in the
17 future we will have other sling materials that have the
18 strength of a synthetic that are even more inert in the
19 vaginal environment. Do you see that?

20 A I do.

21 Q Would you agree that this statement that you
22 made in this article would seem to indicate that the
23 current mesh synthetic mesh materials utilized in the
24 pelvic floor environment are not completely inert?

1 MR. DIPOLA: Object to form.

2 THE WITNESS: I think the statement I
3 was suggesting here was really to make the medical
4 community realize that we shouldn't be complacent with
5 what we have, even though it's very very good, that
6 perhaps one day there will be something even better,
7 and that was really the only intention of that
8 statement. Not really to show that the material we're
9 using now is substandard.

10 BY MR. FAES:

11 Q Do you have an opinion in this case as to
12 whether or not the Prolene material in the TVT is
13 completely inert or not?

14 MR. DIPOLA: Object to form.

15 THE WITNESS: I think the obvious is
16 that anything that's synthetic can't be completely
17 inert, and that was, again, I think the intention of
18 that phrase.

19 BY MR. FAES:

20 Q So you would agree, then, that it would be a
21 positive thing if medical device companies could
22 develop a mesh material that would be more inert than
23 what is on the market currently?

24 A I think we always have to keep pushing the

1 envelope to try to figure out new materials that would
2 be less reactive in a human setting. Is there such a
3 material, I don't know.

4 MR. FAES: I think I'm out of time,
5 unless you really want to give me a long leash. I may
6 want to redirect.

7 Doctor, I could go on, but I think I'm
8 out of time.

9

10 CROSS-EXAMINATION BY MR. DIPOLA

11

12 Q Just a few follow-up questions, Dr. Serels.

13 A Sure.

14 Q In no particular order I'm going to address
15 some of the points that Plaintiff counsel made to you
16 in the last three hours. Are you aware that both laser
17 cut and mechanically cut mesh are still available on
18 the market?

19 A Yes.

20 Q In your 16 years plus of implanting
21 midurethral slings, are you aware of any clinical
22 difference in outcome between mechanically cut mesh and
23 laser cut mesh?

24 A No.

1 Q Is there any level one literature evidence
2 that there's any difference in outcome or complication
3 rate between laser cut mesh and mechanically cut mesh?

4 A No.

5 Q Do you recall when Plaintiff's counsel was
6 asking you about pore size?

7 A Yes.

8 Q Do you know if the current form of the
9 Ethicon product, how the pore size of that product
10 relates to all other mesh pore size products?

11 A It's similar to the other pore sizes, and it
12 fulfills a criteria to make those pores large enough to
13 avoid infections, which would be caused by the lack of
14 one's own body, specifically macrophages getting to the
15 area where the mesh is.

16 Q So is it your understanding, would you agree
17 with me that all the current meshes on the market --
18 strike that.

19 That the Ethicon product mesh is considered a
20 macroporous mesh?

21 A Correct.

22 Q And that by all clinical studies is the mesh
23 that is used to minimize any complication rate?

24 A Correct.

1 Q Do you recall when Plaintiff's counsel asked
2 you about whether you had any complications in your
3 dealings?

4 A Yes.

5 Q Are the complications that you've had in your
6 experience, are they similar to what's been reported in
7 the literature over time?

8 A Specifically relating to slings?

9 Q Yes. I'm sorry, this is all purely related
10 to slings.

11 A Well, we spent a lot of time describing mesh
12 exposures and pain with mesh, that's something I really
13 don't see in my practice. I've always thought that
14 that was due to the placement of the mesh, and the
15 coverage I got, and the dissection planes. As far as
16 voiding dysfunction, urinary tension, that certainly
17 can occur in any situation. I think my rates are lower
18 than the published rates, but they can happen.

19 Q Is it a fair statement to say -- strike that.
20 Do you recall when Plaintiff's counsel gave
21 you a litany of complications that he was associating
22 with mesh?

23 A Correct.

24 Q With the exception of the exposure

1 complication, are all of those risks that Plaintiff
2 counsel mentioned, are they also risks of any surgery
3 that was performed prior to the invention of mesh as a
4 midurethral sling?

5 A That's a great point. The majority if not
6 all with the exception of the exposure are things that
7 you're subjected to with other procedures that are done
8 in the same area even if they're not using material.

9 Q And are all of those complications or
10 untoward events, are all of those itemized untoward
11 events, are they all known events that can happen to
12 not only any pelvic floor surgery, but known to any
13 pelvic floor surgeon?

14 A Yes.

15 Q To that point, do you remember when
16 Plaintiff's counsel asked you about what should and
17 should not be included in the IFU?

18 A Right.

19 Q Is it your opinion that it may be reasonable,
20 but is it necessary for every possible untoward event
21 to be listed in an IFU?

22 MR. FAES: Object to form.

23 THE WITNESS: I do not think it's
24 necessary to have those listed.

1 BY MR. DIPOLA:

2 Q It is necessary?

3 A I do not think it's necessary.

4 Q And why don't you think it's necessary?

5 A This sort of echoes back to what we had
6 spoken about that as a surgeon, you don't really rely
7 on the IFU to understand and to learn and operate.
8 Could you refer to it if you're trying something new,
9 perhaps, but there's many other aspects that go into
10 your training and your ability to do surgery in an IFU.

11 Q Do you discuss complications with your
12 colleagues?

13 A Absolutely.

14 Q Has anyone ever come to you in the last ten
15 years and say, Scott, I found this new complication
16 that I've never heard of before from a midurethral
17 sling placement?

18 MR. FAES: Object to form.

19 THE WITNESS: Sure, yes, it could come
20 up.

21 BY MR. DIPOLA:

22 Q And what would that have been?

23 MR. FAES: Object to form.

24 THE WITNESS: Well, there will be, to

1 your point, certain times you'll have a discussion with
2 another surgeon, and they'll say, oh, my patient got a
3 rash on their face after I put in a polypropylene mesh
4 sling, have you seen that, and could that be related.
5 I mean, there will be all sorts of circumstances that
6 come up, not necessarily as a result of the sling, or
7 what they're doing, but they may want to know if
8 there's a cause and effect. Most of the established
9 complications have, since we've been doing these slings
10 for such a long time, have already been discussed.

11 BY MR. DIPOLA:

12 Q And you personally, you've been implanting
13 slings since, I believe you said, 1998?

14 MR. FAES: Object to form.

15 THE WITNESS: Well, polypropylene mesh
16 slings.

17 BY MR. DIPOLA:

18 Q Let me ask you. When did you start
19 implanting Ethicon's midurethral sling device?

20 A Yes, that was probably '98, '99.

21 Q And since that time how many of these devices
22 would you say that you've implanted in your career?

23 A Polypropylene mesh sling devices?

24 Q Yes.

1 A Thousands.

2 Q Do you remember when plaintiff's counsel was
3 making a litany of what you were not an expert in?

4 MR. FAES: Object to form.

5 THE WITNESS: Yes.

6 BY MR. DIPAOLA:

7 Q Let me ask you potentially, after you've
8 implanted a thousand of these midurethral slings, is it
9 fair to say that you are an expert in how a woman's
10 body reacts to the implantation of mesh devices?

11 MR. FAES: Object to form.

12 THE WITNESS: Yes.

13 BY MR. DIPAOLA:

14 Q Do you remember when Plaintiff's counsel
15 showed you Exhibit 20?

16 A Yes.

17 Q Which was the Project Mint, which he
18 represented was the unrelated Prosima developmental
19 project.

20 MR. FAES: Objection.

21 BY MR. DIPAOLA:

22 Q But he compared that to the TVT device. Do
23 you recall that line of questions?

24 MR. FAES: Object to form.

1 THE WITNESS: Yes.

2 BY MR. DIPAOLA:

3 Q Do you recall that you ranked highest, A
4 repair system that enables a standardized procedure.
5 Do you recall that?

6 A Yes.

7 Q Do you believe as you sit here today that the
8 TVT devices do indeed have a standardized procedure?

9 MR. FAES: Object to form.

10 THE WITNESS: Yes.

11 BY MR. DIPAOLA:

12 Q Do you recall that you also ranked as high
13 as, Requires minimal dissection. Do you, as you sit
14 here today, believe that the TVT product and line of
15 products have the most minimal dissection possible for
16 their installation?

17 MR. FAES: Object to form.

18 THE WITNESS: Yes.

19 BY MR. DIPAOLA:

20 Q As you sit here today, and you ranked
21 previously as high, System components designed to
22 maintain correct anatomic position, and that was ranked
23 five out of five. As you sit here today, do you
24 believe that that is also applicable to the current

1 device that is the TVT device?

2 MR. FAES: Object to form.

3 THE WITNESS: Yes.

4 BY MR. DIPOLA:

5 Q Also, you rank, Procedure that is designed to
6 avoid unintended trauma. You ranked that high, five
7 out of five again. Again, as you sit here today as an
8 expert in implanting over 2,000 of these devices, do
9 you sit here and can you say that the TVT device also
10 is designed to avoid unintended trauma?

11 MR. FAES: Object to form.

12 THE WITNESS: Yes.

13 BY MR. DIPOLA:

14 Q Again, ranking high, A system with minimal
15 chance for complications. Do you believe that the TVT
16 system, as you sit here today as an expert, has been
17 designed for a minimal chance of complications?

18 MR. FAES: Object to form.

19 THE WITNESS: Yes. I mean, that was the
20 intention.

21 MR. DIPOLA: I have nothing else.

22 MR. FAES: I have like five questions.

23

24

1 REDIRECT EXAMINATION BY MR. FAES

2

3 Q Doctor, are you aware of any clinical study
4 that has specifically compared the safety and
5 complication rates of the mechanically cut TVT
6 retropubic device versus the laser cut mesh TVT
7 retropubic device?

8 A Not off the top of my head, no.

9 Q Are you relying on the Amid standard for your
10 opinion that the TVT mesh is a type one macroporous
11 mesh?

12 A Yes.

13 Q You know that that standard was developed in
14 1998 originally for hernia meshes, correct?

15 A Yes.

16 Q Do you know whether or not Amid thinks that
17 that standard doesn't apply to the type of mesh in
18 TVT?

19 MR. DIPOLA: Object to the form.

20 THE WITNESS: I'm not familiar with his
21 opinion on the TVT device, no.

22 BY MR. FAES:

23 Q Have you ever seen anything from Ethicon
24 scientists and engineers stating that the Amid standard

1 is outdated as of 2005?

2 MR. DIPOLA: Object to form.

3 THE WITNESS: No.

4 BY MR. FAES:

5 Q Is it fair to say that if you did see
6 statements from Ethicon scientists and engineers who
7 are designing mesh products that stated that the Amid
8 standard was outdated, you would disagree with that?

9 MR. DIPOLA: Object to form.

10 THE WITNESS: I'm not sure I can answer
11 that as yes/no. I would have to hear what their
12 thought process was.

13 BY MR. FAES:

14 Q Doctor, you talked a lot today about your
15 experience with polypropylene mesh devices and
16 midurethral slings, you understand that you are here
17 today to give an expert opinion specific to just the
18 TVT device, correct?

19 A Yes.

20 Q And you would agree that the polypropylene
21 mesh that's in the TVT is different than the mesh
22 that's used in many competitor devices that you've used
23 such as AMS's, Caldera's, or Boston Scientific slings,
24 correct?

1 MR. DIPOLA: Object to form.

2 THE WITNESS: I think they're similar
3 enough.

4 BY MR. FAES:

5 Q But you understand that there are basic
6 differences in the type of raw material that's used,
7 correct?

8 A I'm not an expert on raw materials.

9 Q So you don't know one way or the other --

10 A Correct.

11 Q -- if the raw material that's used in the TVT
12 is different from the material that's used in say
13 Boston Scientific, or AMS's, or Caldera's slings?

14 A Correct.

15 MR. DIPOLA: Object to the form.

16 BY MR. FAES:

17 Q Have you done any kind of study into whether
18 or not the differences in raw material would make a
19 difference in the clinical effects of the sling?

20 MR. DIPOLA: Object to form.

21 THE WITNESS: I have not.

22 MR. FAES: That's all the questions I
23 have. Thank you for your time, Doctor.

24 (Deposition concluded at 8:00 p.m.)

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ACKNOWLEDGMENT OF DEPONENT

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I, _____, do

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hereby certify that I have read the

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foregoing pages, and that the same is

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a correct transcription of the answers

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given by me to the questions therein

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propounded, except for the corrections or

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changes in form or substance, if any,

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noted in the attached Errata Sheet.

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SCOTT SERELS, M.D.

DATE

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Subscribed and sworn

to before me this

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_____ day of _____, 20____.

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My commission expires: _____

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Notary Public

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CERTIFICATE OF REPORTER

I, Robin Balletto, a Registered Professional Reporter/Notary Public within and for the State of Connecticut, do hereby certify there came before me, on the 7th day of April, 2016, the following named person, to wit: SCOTT SERELS, M.D., who was by me duly sworn to testify to the truth and nothing but the truth; that he was thereupon carefully examined upon his oath and his examination reduced to writing under my supervision; that this deposition is a true record of the testimony given by the witness.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition is taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

WITNESS my hand and affixed my seal this 8th day of April, 2016.

Robin Balletto, RMR

My commission expires: October 31, 2018